DO CELLULAR AND OTHER WIRELESS DEVICES INTERFERE WITH SENSITIVE MEDICAL EQUIPMENT?

Y 4.G 74/7:C 33/8

Do Cellular and Other Wireless Devi...

HEARING

BEFORE THE

INFORMATION, JUSTICE, TRANSPORTATION,
AND AGRICULTURE SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

OCTOBER 5, 1994

Printed for the use of the Committee on Government Operations

OCT 0 1 1997

U.S. GOVERNMENT PRINTING OFFICE
85–813 WASHINGTON : 1997

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-054917-5

18

DO CELLULAR AND OTHER WIRELESS DEVICES INTERFERE WITH SENSITIVE MEDICAL EQUIPMENT?

Y 4.G 74/7:C 33/8

Do Cellular and Other Wireless Devi...

HEARING

BEFORE THE

INFORMATION, JUSTICE, TRANSPORTATION,
AND AGRICULTURE SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

OCTOBER 5, 1994

Printed for the use of the Committee on Government Operations

OCT 3 1 1997

U.S. GOVERNMENT PRINTING OFFICE
85–813 WASHINGTON : 1997

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-054917-5

COMMITTEE ON GOVERNMENT OPERATIONS

JOHN CONYERS, Jr., Michigan, *Chairman*

CARDISS COLLINS, Illinois
HENRY A. WAXMAN, California
MIKE SYNAR, Oklahoma
STEPHEN L. NEAL, North Carolina
TOM LANTOS, California
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
JOHN M. SPRATT, Jr., South Carolina
GARY A. CONDIT, California
COLLIN C. PETERSON, Minnesota
KAREN L. THURMAN, Florida
BOBBY L. RUSH, Illinois
CAROLYN B. MALONEY, New York
THOMAS M. BARRETT, Wisconsin
DONALD M. PAYNE, New Jersey
FLOYD H. FLAKE, New York
JAMES A. HAYES, Louisiana
CRAIG A. WASHINGTON, Texas
BARBARA-ROSE COLLINS, Michigan
CORRINE BROWN, Florida
MARJORIE MARGOLIES-MEZVINSKY, Pennsylvania
LYNN C. WOOLSEY, California
GENE GREEN, Texas
BART STUPAK, Michigan

WILLIAM F. CLINGER, Jr., Pennsylvania
AL McCANDLESS, California
J. DENNIS HASTERT, Illinois
JON L. KYL, Arizona
CHRISTOPHER SHAYS, Connecticut
STEVEN SCHIFF, New Mexico
CHRISTOPHER COX, California
CRAIG THOMAS, Wyoming
ILEANA ROS-LEHTINEN, Florida
DICK ZIMMER, New Jersey
WILLIAM H. ZELIFF, Jr., New Hampshire
JOHN M. McHUGH, New York
STEPHEN HORN, California
DEBORAH PRYCE, Ohio
JOHN L. MICA, Florida
ROB PORTMAN, Ohio
FRANK D. LUCAS, Oklahoma

BERNARD SANDERS, Vermont (Independent)

JULIAN EPSTEIN, *Staff Director*
MATTHEW R. FLETCHER, *Minority Staff Director*

INFORMATION, JUSTICE, TRANSPORTATION, AND AGRICULTURE SUBCOMMITTEE

GARY A. CONDIT, California, *Chairman*

MAJOR R. OWENS, New York
KAREN L. THURMAN, Florida
LYNN C. WOOLSEY, California
BART STUPAK, Michigan

CRAIG THOMAS, Wyoming
ILEANA ROS-LEHTINEN, Florida
STEPHEN HORN, California

EX OFFICIO

JOHN CONYERS, Jr., Michigan
WILLIAM F. CLINGER, Jr., Pennsylvania

JOHN EDGELL, *Professional Staff Member*
AURORA OGG, *Clerk*
DIANE M. MAJOR, *Minority Professional Staff*

CONTENTS

Page

Hearing held on October 5, 1994 1

Statement of:

- Stanley, Thomas P., chief engineer, Office of Plans and Policy, Federal Communications Commission 8
- Swanson, Charles, vice president, Regulatory Affairs, Pacing, Medtronics, Inc., representing the Health Industry Manufacturers Association; and John Stupka, president and chief executive officer, Southwestern Bell Mobile Systems, representing the Cellular Telecommunications Industry Association 23

Letters, statements, etc., submitted for the record by:

- Condit, Hon. Gary A., a Representative in Congress from the State of California, prepared statement of 3
- Stanley, Thomas P., chief engineer, Office of Plans and Policy, Federal Communications Commission:
  - Information concerning EMI protection distance 20
  - Prepared statement of 12
- Stupka, John, president and chief executive officer, Southwestern Bell Mobile Systems, representing the Cellular Telecommunications Industry Association, prepared statement of 38
- Swanson, Charles, vice president, Regulatory Affairs, Pacing, Medtronics, Inc., prepared statement of 29
- Thomas, Hon. Craig, a Representative in Congress from the State of Wyoming, prepared statement of 7
- Thurman, Hon. Karen L., a Representative in Congress from the State of Florida, prepared statement of 58

DO CELLULAR AND OTHER WIRELESS DEVICES INTERFERE WITH SENSITIVE MEDICAL EQUIPMENT?

WEDNESDAY, OCTOBER 5, 1994

House of Representatives,
Subcommittee on Information, Justice,
Transportation, and Agriculture,
Committee on Government Operations,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:02 a.m., in room 2203, Rayburn House Office Building, Hon. Gary A. Condit (chairman of the subcommittee) presiding.

Present: Representatives Condit, Thurman, Thomas and Horn.

Staff present: John Edgell, professional staff member; Aurora Ogg, clerk; and Diane Major, minority professional staff, Committee on Government Operations.

Mr. Condit. Good morning. This morning's subcommittee hearing addresses recent reports of alleged cellular and wireless-related interferences with sensitive medical devices and equipment. This hearing is an initial fact-finding effort to identify the scope of the problem, to hear from the Federal Communications Commission and two affected industry groups, and to consider possible private and public-sector responses.

Today, many experts are concerned that medical devices, if not properly designed to shield or protect sensitive electronic microchips, may be particularly vulnerable to unintended but potentially serious EMI interference that may cause the device to malfunction.

The window of opportunity for the two industry sectors to address this possible problem is here. The private sector needs to solve this problem and we need to solve it quickly. As we enter a new stage of anytime, anywhere wireless service, we must take every precaution to assure consumers of the safety and the effectiveness of new technology. As a pro-business, pro-technology Democrat, I want to do everything I can to help make this successful. This subcommittee has a responsibility to ask tough questions, find facts, and take every step to assure a smooth, natural transition into a new era. Let this be an act of responsibility.

In June 1994, I asked the General Accounting Office to look into reported cases where cellular phones and other wireless communications devices have apparently caused disruption in the operation of sensitive medical devices such as pacemakers, electric wheelchairs, hearing aids, blood gas pumps, and heart monitors.

The GAO was specifically asked to review the work of the FCC and to make recommendations about possible legislative or regulatory policies. The GAO will provide formal findings next year.

Cellular and wireless providers and manufacturers, medical device manufacturers, health care providers, hospitals and consumers benefit from an understanding of this issue and we must work together to assure the safety and effectiveness of these technologies.

Two Federal agencies have primary oversight responsibility related to this particular issue—the FCC, which manages the public airwaves and oversight of safety of cellular and wireless devices; the Food and Drug Administration, which oversees the safety and efficacy of medical devices. This subcommittee, of course, oversees the FCC.

Today's hearing will consist of two panels. The first panel will consist of Dr. Thomas Stanley, chief engineer of the FCC. The second panel will consist of representatives of the Cellular Telecommunications Industry Association and the Health Industry Manufacturers' Association. And we're delighted to have all of you here this morning.

We are going to make this hearing as constructive as we possibly can and we are going to do it in as short a period of time as we can, given the schedule today on the floor. So if we move you along quickly, do not take offense to that. We will be back at you at a different time. So we appreciate you all being here.

[The prepared statement of Hon. Gary A. Condit follows:]

STATEMENT OF REP. GARY A. CONDIT, CHAIRMAN
SUBCOMMITTEE ON
INFORMATION, JUSTICE, TRANSPORTATION AND AGRICULTURE,
HOUSE GOVERNMENT OPERATIONS COMMITTEE

"DO CELLULAR AND OTHER WIRELESS DEVICES INTERFERE WITH SENSITIVE MEDICAL EQUIPMENT?

Are Pacemakers, Hearing Aids, Apnea Monitors, Blood Pumps and Other Sophisticated Medical Devices Affected by Outside Electromagnetic Interference (EMI) from Cellular and Other Wireless Devices?"

Wednesday, October 5, 1994
2203 Rayburn House Office Building

Good morning. This morning's Subcommittee hearing addresses recent reports of alleged cellular- and wireless-related interference with sensitive medical devices and equipment. This hearing is an initial "fact-finding" effort to identify the scope of the problem, to hear from the Federal Communications Commission and two affected industry groups, and to consider possible private- and public-sector solutions.

In June, 1994, I asked the General Accounting Office (GAO) to look into reported cases where cellular phones and other wireless communications devices have apparently caused disruptions in the operations of sensitive medical devices such as pacemakers, electric wheelchairs, hearing aids, blood gas pumps, apnea (Sudden Infant Death Syndrome, or SIDS) monitors, and heart monitors. Three recent news reports describe the situation:

> From the June 15, 1994 Wall Street Journal: "As life-saving electronic medical equipment becomes more sophisticated and sensitive, evidence has begun to pile up that these instruments are vulnerable to increasing levels of electromagnetic interference -- the waves given off by radios, cellular phones and television sets."
>
> From the June 16, 1994 Communications Daily: "At least 5 deaths have been tied to EMI problem, according to FDA records. The problem isn't limited to cellular phones. Some EMI comes from medical devices themselves that use wireless transmissions to report patient data. Other devices such as pagers, walkie-talkies and cordless phones also have been reported to cause problems with medical devices."
>
> From the July/August 1994 Microwave News, "Digital Cellular Phones Can Disrupt Implanted Pacemakers": "New studies conducted in Switzerland and in Italy show that cardiac pacemakers implanted in patients can be affected by electromagnetic interference (EMI) from digital cellular telephones."

The GAO was specifically asked to review the work of the FCC and to make recommendations about possible legislative or regulatory policies. The GAO will provide formal findings next year.

As telecommunications enters a new stage of "anywhere, anytime" wireless service, we must take every precaution to assure the consuming public of the safety and effectiveness of new technologies. The wireless world offers many promising opportunities, providing consumers with benefits perhaps beyond our imaginations. This Subcommittee, with oversight of the Federal Communications Commission, stands ready to assist the development of dynamic new technologies. But it is also our responsibility to ask tough questions, find facts, and take every step to assure a smooth, natural transition in a new telecommunications era.

Today we will ask questions and seek answers about reports of unintended interference caused by cellular and other wireless devices with sensitive medical devices.

Electromagnetic interference, or EMI as it is commonly referred to, is a disruption caused when radio waves emitted by one type of device interfere with the normal operation of another type of device. For example, stray electromagnetic emissions are suspected of causing electronic imaging devices to return false readings and motorized wheelchairs to move unexpectedly. Many experts in the field are concerned that medical devices, if not properly designed to shield, or protect, sensitive electronic microchips, may be particularly vulnerable to unintended, but potentially serious, EMI that may cause the device to malfunction.

Two federal agencies have primary oversight responsibility related to this particular issue: the Federal Communications Commission (FCC), which manages the public airwaves, oversees the safety and efficacy of cellular and wireless devices, and is generally responsible for regulating devices which emit electromagnetic energy, and the Food and Drug Administration (FDA), which oversees the safety and efficacy of medical devices.

The FCC's oversight of the emerging telecommunications industry will increase as the expected "information superhighway" develops. As issues such as cellular- and wireless-related EMI emerge, FCC will be increasingly expected to develop policy options and to increase its oversight efforts. The FCC will testify about its involvement in overseeing the safety and efficacy of cellular and wireless devices, its observations about alleged EMI issues, and policy recommendations in this area.

The FDA's Center for Medical Devices has a major role in the discussion and resolution of this issue. An August, 8, 1994 FDA "Talk Paper" stated: "the agency has received a number of reports in recent years of possible EMI-related problems with medical devices -- some resulting in serious injury or death. Electronic medical devices can be susceptible to interference if they are not designed to be protected against it. Common sources of EMI include cellular phones, police, fire or ambulance mobile communications equipment, radio and TV transmitters, amateur radio transmitters and CB radio transmitters.

Affected parties -- especially cellular and wireless providers and manufacturers, medical device manufacturers, health care providers, hospitals, and consumers -- benefit from an understanding of the issues and the need to work together to assure the safety and efficacy of both cellular and wireless devices and sensitive medical devices and equipment.

A technical seminar, jointly sponsored by the Cellular Telecommunications Industry Association (CTIA) and the Health Industry Manufacturers Association (HIMA), was held in Dallas, TX, on September 29 & 30, 1994 for design engineers and technical electronic experts from both manufacturing industries. Such cooperative efforts are a sign that the respective industry sectors recognize the potential scope of the problem and are willing to take appropriate steps to establish new compatibility standards that assure the safety and efficacy of both industries' products. The Subcommitee will continue to monitor these developments.

Today's hearing will consist of two panels. Panel One will consist of Dr. Thomas Stanley, Chief Engineer of the FCC. Panel Two will consist of representatives of the Cellular Telecommunications Industry Association (CTIA) and the Health Industry Manufacturers Association (HIMA).

Mr. CONDIT. We have a brief video, so bear with us. We're going to play the video and then I'm going to let Mr. Horn speak.

How long is the video? OK, let's take the 30-second video, then Mr. Horn can make his comment.

This is an FDA tape. It is not a Hollywood production, so bear with us. There is no sound to this, so I am going to sort of narrate for you.

You will notice the antenna there in the middle of the picture. The antenna emits different levels of electronic pulse similar to wireless devices. The wheelchair is moving as a result of the pulse. It is not moving on its own electricity. We do not know the level of electronic emission, but it is clear that the interference problem can be demonstrated. It is not all that exciting, but I think you get the basic idea.

That's basically it.

Mr. Horn, would you like to make an opening statement?

Mr. HORN. I'm just going to submit Mr. Thomas' statement for the record, the ranking Republican on the subcommittee.

[The prepared statement of Hon. Craig Thomas follows:]

CRAIG THOMAS
WYOMING AT LARGE

WASHINGTON OFFICE
LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON DC 20515-5001
(202) 225-2311

Congreſs of the United States
House of Repreſentatives
Waſhington, DC 20515-5001

CONGRESSMAN CRAIG THOMAS

OPENING STATEMENT
HEARING, "ELECTROMAGNETIC COMPATIBILITY BETWEEN WIRELESS TECHNOLOGY AND MEDICAL DEVICES"

October 5, 1994
ROOM 2203 RAYBURN HOUSE OFFICE BUILDING

Thank you, Mr. Chairman. I look forward to hearing from our witnesses today regarding their efforts to make medical equipment and wireless technology more compatible. As technology continues to advance both in the medical and telecommunication fields, compatibility issues will always be present -- and are best left to industry to solve.

Frankly, the federal government does not have a good track record when it comes to keeping the marketplace competitive. The regulatory assaults on businesses by the Clinton administration are staggering. As of March, the number of pages in the Federal Register -- the publication listing all regulations -- had reached 69,700. The highest level since 1980. I hope the "after effects" of today's hearing do not add to this number.

The issue of wireless technology interfering with the electronic circuitry or other receptive components in medical devices, obviously needs to be explored. However, I would advise my colleagues against issuing a new set of regulations. The costs associated with compliance compared to the actual risk of public safety, do not justify new unfunded federal mandates.

The private sector has taken the initiative. Last weekend, the medical and wireless industries convened a conference to address interference problems. Four of the largest service and manufacturing companies -- AT&T, Motorola, Southwestern Bell Mobil Systems and McCaw Cellular Communications, Inc. -- have also joined in establishing the Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma. And, furthermore, private standard-setting organizations have been instrumental in recommending guidelines for electromagnetic interaction. These are private-sector solutions that do not need to be mandated by the federal government.

If there is one issue that should be the focus of today's hearing, it should be how to keep the marketplace healthy rather than how to impede progress.

Mr. CONDIT. Thank you, Mr. Horn. I thank you for being here this morning.

Mr. Stanley.

Mr. STANLEY. Thank you very much.

Mr. CONDIT. We have a policy of swearing in all witnesses. Will you please raise your right hand.

[Witness sworn.]

Mr. CONDIT. Thank you. Dr. Stanley, you may proceed.

STATEMENT OF THOMAS P. STANLEY, CHIEF ENGINEER, OFFICE OF PLANS AND POLICY, FEDERAL COMMUNICATIONS COMMISSION

Mr. STANLEY. All right, thank you.

Mr. Chairman, members of the subcommittee, I appreciate this opportunity to testify about operational problems that medical devices may encounter when exposed to electromagnetic energy. My name is Tom Stanley, Chief Engineer, Office of Plans and Policy at the Federal Communications Commission. I will provide some technical information on background and our recommendations for addressing the problem.

As we all know, this Nation and the world are undergoing a communications revolution. The United States is at the forefront of this revolution with private industry leading the way, as it should. The new national information infrastructure will increase productivity, create jobs and improve education. Our job at the FCC is to make sure that the competition is open and fair, that innovation proceeds as rapidly as possible and that all Americans have an opportunity to participate in the new world that communications technology is creating.

Technological innovation is also spawning rapid advances in medical electronics and an increasing use of electronic devices in health monitoring and treatment. While our records and those of the FDA reveal only a small number of complaints of medical device malfunctions ascribed to communication services, the number is likely to grow as both medical and communications devices proliferate.

The FCC rules treat two general kinds of interference: Interference between and among our licensed communications services, such as cellular radio, telephone and television; and interference from communications devices that we authorize, such as cordless telephones with television or radio.

The FCC rules and enforcement procedures remedy these forms of interference by relying on separations in terms of frequency, power, time and/or distance.

Interference of the sort we are exploring today is a specific example of what is called electromagnetic compatibility, or EMC, a term that generally signifies the capability of electronic devices, including medical devices, to function properly in an electromagnetic environment. The more immune a particular device is to electromagnetic signals, the better it functions in a variety of situations and locations.

Sources of electromagnetic signals usually transmit in all directions at once or at least in a wide swath. These waves, once disseminated, cannot be reprogrammed to change frequencies or avoid objects in their paths. If the medical device lies in the path of a signal with sufficient power and on frequencies to which the device is susceptible, the operation of the medical device can be disrupted.

Semantics aside, the crux of the problem is this: It is impossible to know in many cases in advance the transmissions to which a medical device will be exposed. A defibrillator in an ambulance may be driven right by a powerful TV transmitter in one emergency and then parked in the midst of a dozen police and fire radios on another run. Of course, the ambulance itself will also have a radio that is constantly transmitting and receiving.

An apnea monitor will be subject to the normal broadcast signals received in the home but may also suddenly be in the range of a utility repair truck's radio if a nearby water main breaks or an electrical line goes down. A wheelchair occupant, we hope, will have ready access throughout our communities and he or she may, therefore, go in and out of range of all kinds of transmissions.

Those who originate wireless transmissions usually cannot know when there is a medical device within effective range of their transmissions, nor can they know whether the fixed frequency and power on which they are licensed to operate will interfere with any of the medical devices that their transmissions might encounter. It is also usually impossible for the manufacturers of medical devices to know with precision all the transmissions a device would have to tune out in order to avoid EMC conflicts throughout its service life.

Although operators and manufacturers cannot know when a particular device or particular transmission will intersect, we do know the broad range of powers and frequencies on which the vast array of modern communications devices operate. Therefore, medical devices can be designed, shielded, or filtered to make sure that they will operate with increased immunity in the electromagnetic spectrum we encounter as a matter of course in our modern world. This is a realistic and workable solution to minimizing EMC problems in most, if not all, cases.

It is worth noting that even where we know the exact source of interference, as where a nearby radio transmission station interferes with a homeowner's telephone, the principle solution is to place a filter on the telephone. Similarly, when CB radios were found to be interfering with truck braking mechanisms, the problem was solved by appropriate shielding of the braking systems.

In solving EMC problems, generally, the transmissions can rarely be altered except by turning them off. The passive device, however, can generally be made less susceptible to EMI, electromagnetic interference. Precisely for these reasons, the European community responded to concerns about EMC and medical devices by addressing the susceptibility of the devices rather than attempting to restrict communications services. Medical devices sold in Europe must now meet immunity standards for electromagnetic compatibility.

With respect to stationary medical facilities, it has been suggested that EMC problems could be prevented by managing radio transmissions within and around the medical facility. Prohibitions on certain transmitting sources such as cellular telephones, pagers and hand-held radios within given distances of certain critical hospital areas have been decreed in some hospitals. We believe that this response ought to be regarded as a measure of last resort.

The importance of pagers and other communications devices to medical and other public safety personnel makes prohibiting transmissions a self-defeating measure. The expanding use of telemedicine in which doctors at one facility conduct video consultations with doctors at distant facilities, sometimes by wireless communications, makes limiting transmissions even more of an undesirable approach to solving EMC problems. Advances in medical electronics devices and in communications suggests that we need more, not less, of both technologies.

Again, a more comprehensive, long-term and practical solution to the EMC problem in most cases, whether the medical devices are mobile or stationary, in a home or in a hospital, is to make the devices more immune to undesirable transmissions. Research is under way in this area and we do not believe that regulation will be necessary if the medical device industry will adopt and adhere to voluntary standards.

The Communications Act does not authorize the FCC to set EMC standards with one exception—home electronics equipment. The Commission has not exercised this authority because we felt that the costs associated with complying with mandatory immunity standards for the equipment would exceed the benefit obtained, given the relatively limited number of interference problems that exist. In specific cases, televisions, for example, the industry has adopted voluntary immunity standards at the urging of the FCC.

The Center for Devices and Radiological Health of the U.S. Food and Drug Administration does appear to have the requisite authority to take the lead governmental role in encouraging medical device immunity. The CDRH, formed in 1982 from the merger of two FDA bureaus, is responsible for approving the manufacture and sale of medical devices in the United States.

CDRH has been aware of the EMC problem for some time. It has conducted research and is currently working on immunization guidance for the medical device industry. CDRH already requires that EMC test data accompany premarketing notification submissions to the CDRH, applications for FDA approval, for some devices. The CDRH has the authority to disapprove the marketing of devices that do not conform to its EMC guidance.

The FCC stands ready to assist CDRH in tackling this problem. Our staffs have met informally for years and we're announcing today that our two agencies will begin interagency consultations to exchange information on the most effective approaches to the EMC problem within our respective jurisdictional areas. Together with the medical device and communications industry, which are already researching EMC problems, we want to make sure that the research is comprehensive and that no reasonable approach is overlooked.

This cooperative approach is the best way to ensure the safe operation of medical devices without disrupting our networks of communications. Particularly in light of the explosive growth of communications and medical electronics, which shows no signs of abating, this cooperative effort will assure that we seek out the common sense and technically correct responses.

Thank you again for this opportunity to testify on this important matter, and I'd be happy to respond to any questions.

[The prepared statement of Mr. Stanley follows:]

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to testify about operational problems that medical devices may encounter when exposed to electromagnetic energy. I am Dr. Thomas P. Stanley, Chief Engineer, Office of Plans and Policy, the Federal Communications Commission. I will provide some technical background information and our recommendations for addressing the problem.

As we all know, this nation and the world are undergoing a communications revolution. The United States is at the forefront of this revolution, with private industry leading the way, as it should. The new national information infrastructure will increase productivity, create jobs, and improve education. Our job at the FCC is to make sure that competition is open and fair, that innovation proceeds as rapidly as possible and that all Americans have an opportunity to participate in the new world that communications technology is creating.

Technological innovation is also spawning rapid advances in medical electronics and an increasing use of electronic devices in health monitoring and treatment. While our records and those of the Food and Drug Administration reveal only a small number of complaints of medical device malfunctions ascribed to communications services, the number is likely to grow as both medical and communications devices proliferate.

The FCC's rules treat two general kinds of interference:

1) Interference between and among our licensed communications services, such as cellular radio telephone and television, and

2) Interference from communications devices that we authorize, such as cordless phones, with television or radio.

The FCC rules and enforcement procedures remedy these forms of interference by relying on separations in terms of frequency, power, time and/or distance.

Interference of the sort that you are exploring today is a specific example of what is called electromagnetic compatibility, or EMC, a term that generally signifies the capability of electronic devices, including medical devices, to function properly in an electromagnetic environment. The more immune a particular device is to electromagnetic signals, the better it functions in a variety of situations and locations.

Sources of electromagnetic signals usually transmit in all directions at once, or at least in a wide swath. These waves, once disseminated, cannot be programmed to change frequencies or avoid objects in their paths. If a medical device lies in the path of a signal of sufficient power and on frequencies to which the device is susceptible, the operation of the medical device can be disrupted.

Semantics aside, the crux of the problem is this: it is impossible in many cases to know in advance the transmissions to which a medical device will be exposed. A defibrillator in an ambulance may be driven right by a powerful TV transmitter on one emergency run and parked in the midst of a dozen police and fire radios on another run. Of course, the ambulance itself will also have a radio that is constantly transmitting and receiving. An apnea monitor will be subjected to the normal broadcast signals received in the home but may also suddenly be in range of a utility repair truck's radio if a nearby water main breaks or an electrical line goes down. A wheelchair occupant, we hope, will have ready access throughout our communities, and he or she may therefore go in and out of range of all kinds of transmissions.

Those who originate wireless transmissions usually cannot know when there is a medical device within effective range of their transmissions. Nor can they know whether the fixed frequency and power on which they are licensed to operate will interfere with any of the medical devices that their transmissions might encounter. It is also usually impossible for the manufacturers of medical devices to know with precision all the transmissions a device would have to "tune out" in order to avoid EMC conflicts throughout its service life.

Although operators and manufacturers cannot know when a particular device and a particular transmission will intersect, we do know the broad range of powers and frequencies on which the vast array of modern communications devices operate. Therefore, medical devices can be designed, shielded or filtered to make sure that they will operate with increased immunity in the electromagnetic spectrum we encounter as a matter of course in our modern world. This is a realistic and workable solution to minimizing EMC problems in most, if not all, cases.

It is worth noting that even where we know the exact source of interference, as where a nearby radio station transmitter interferes with a homeowner's telephone, the principal solution is to place a filter on the phone. Similarly, when CB radios were found to be interfering with truck braking mechanisms, the problem was solved by appropriate shielding of the braking systems.

In solving EMC problems generally, the transmission can rarely be altered, except by turning it off; the passive device, however, can generally be made less susceptible to EMC. Precisely for these reasons, the European Community responded to concerns about EMC and medical devices by addressing the susceptibility of the devices rather than attempting to restrict communications services. Medical devices sold in Europe must now meet immunity standards for electromagnetic compatibility.

With respect to stationary medical facilities, it has been suggested that EMC problems could be prevented by managing radio transmissions within and around the medical facility. Prohibitions on certain transmitting sources such as cellular telephones, pagers, or hand-held radios within given distances of certain critical hospital areas have been decreed in some hospitals. We believe that this response ought to be regarded as a measure of last resort.

The importance of pagers and other communications devices to medical and other public safety personnel makes prohibiting transmissions a self-defeating measure. The expanding use of telemedicine, in which doctors at one facility conduct video consultations with doctors at distant facilities, sometimes by wireless communications, makes limiting transmissions even more of an undesirable approach to resolving EMC problems Advances in medical electronics devices and in communications suggest that we need more, not less, of both technologies.

Again, the more comprehensive, long-term and practical solution to the EMC problem in most cases, whether the medical devices are mobile or stationary, in a home or in a hospital, is to make the medical devices more immune to undesired transmissions. Research is underway in this area and we do not believe that regulation will be necessary if the medical device industry will adopt and adhere to voluntary standards.

The Communications Act does not authorize the FCC to set EMC standards, with one exception: home electronics equipment. The Commission has not exercised this authority because we have felt that the costs associated with complying with mandatory immunity standards for the equipment would exceed the benefit obtained, given the relatively limited number of interference problems that exist. In specific cases -- televisions, for example -- the industry has adopted voluntary immunity standards at the urging of the FCC.

The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration does appear to have the requisite authority to take the lead governmental role in encouraging medical device immunity. The CDRH, formed in 1982 from the merger of two FDA bureaus, is responsible for approving the manufacture and sale of medical devices in the United States. CDRH has been aware of the EMC problem for some time, has conducted research and is currently working on immunization guidance for the medical device industry. CDRH already requires that EMC test data accompany pre-marketing notification submissions to the CDRH (applications for FDA "approval") for some devices. CDRH has the authority to disapprove the marketing of devices that do not conform to its EMC guidance.

The FCC stands ready to assist CDRH in tackling this problem. Our staffs have met informally for years and we are announcing today that our two agencies will begin inter-agency consultations to exchange information on the most effective approaches to the EMC problem within our respective jurisdictional areas. Together with the medical device and communications industries, which are already researching EMC problems, we want to make sure that research is comprehensive and that no reasonable approach is overlooked.

This cooperative approach is the best way to assure the safe operation of medical devices without disrupting our networks of communications. Particularly in light of the explosive growth of communications and medical electronics, which shows no signs of abating, this cooperative effort will assure that we seek out the common-sense and technically correct responses.

Thank you again for the opportunity to testify on this important matter. I will be glad to answer your questions.

Mr. CONDIT. Thank you, Dr. Stanley.

The FCC auction of spectrum sell is clearly a success, raising more than $8 million. The next auction is scheduled for late October, I believe. The FCC may have a conflict. The FCC wants to maximize the value of emerging wireless communication, but some are concerned that the emergent problems, like interference with medical devices, may be overlooked while the spectrum sell is going on.

Can you explain to us how we balance the two?

Mr. STANLEY. Tomorrow, the FCC celebrates the 60th anniversary of the Communications Act, going way back to 1934. The act itself has set up in almost every dimension a set of rules that go very much to the public interest aspects of establishing communications. Virtually all of our rules, basically, go to the public interest aspects.

We're concerned, of course, with modernizing communications and bringing the fruits of technology to the public, but the basic public interest findings certainly take precedence over any other aspect.

Mr. CONDIT. Could you provide the subcommittee with a short description of the difference between digital phones and analogue phones? I assume the United States will soon become digital, and it might be good for us to get a definition from you.

Mr. STANLEY. In almost all areas that the FCC regulates, communications are going from analog to digital. In analog communications, the signals vary continuously to reflect, say, voice level or picture quality. In digital communications, the signals are either ones or zeros. The signal's either on or off. This discrete, as opposed to continuous, form of communications has several benefits in terms of transmission and processing, storage and great efficiencies, specifically with regard to storage and memory capability. So it is a step to the future in terms of modernization.

Mr. CONDIT. A recent issue of Microwave News detailed concerns about the experience of a new digital cellular telephone in Europe. The article claims that the digital cellular telephone interferes with pacemakers. Are you aware of this article and the situation there, and what is the FCC response or do they have a response to that article?

Mr. STANLEY. We are very much aware of the developments. The research, as we understand it or have seen in some of the reports, is still mixed. In a nutshell, it appears as though the standard in use throughout Europe and in some parts of Asia appears to have some potential to interfere with pacemakers. Other conflicting research from Asia suggests perhaps that's not the case.

In any case, in the United States, I'm told that the FDA intends to undertake some testing in this area to get some of the facts straight. So we look to FDA very much to see how they are approaching the problem and that's our principal response.

Mr. CONDIT. Will the testing that is planned be completed before mass production begins and digital cellular phones are sold to the public?

Mr. STANLEY. I'm not familiar with the specific testing. The particular standard under scrutiny is the European standard. It is not clear that that standard would be the one introduced in the United

States. I have other reasons to believe that perhaps the situation in the United States might be slightly better than in Europe.

The standards in the United States being looked at have significantly less power and insofar as that's a factor, that might ameliorate some of the impact. As to the timing of the testing, I'm not familiar with the schedule that the FDA has in this area. We can certainly talk to them and find out.

Mr. CONDIT. The FDA recently prepared a two-page EMI protectant distance drafts dated August 15, 1994. The FDA has shared the document with the FCC. It appears as though it is a first rough cut at a new capability standard for cellular and wireless transmitters and medical devices. Have you seen the document?

Mr. STANLEY. Yes.

Mr. CONDIT. Can you describe its contents for the subcommittee?

Mr. STANLEY. Sure. The document basically is a table. Along one dimension, they show different levels of immunity, say for example, increasing immunity. Along the other dimension of the table are distances that, for example, a medical device could come in proximity to a transmitter. So it is an attempt to balance immunity of devices with how close you can come in a particular situation.

It should be viewed largely as a draft research development. It is not an official position of any agency. Specifically, it is an attempt to understand how a particular single radiator might affect the environment around it.

Most people should realize that there are other aspects, for example, whether there are reflections, what particular environment the emitter is in, whether there is more than one emitter. So again, it is a simple, perhaps oversimple, model of reality, but it certainly is a scientific approach to trying to understand radiation and its impact.

Mr. CONDIT. Dr. Stanley, would you provide the subcommittee a formal written statement for the record on this document?

Mr. STANLEY. Certainly.

Mr. CONDIT. And from just what you explained to us?

Mr. STANLEY. Certainly.

[The information referred to follows:]

"EMI Protection Distance"

The document referred to is entitled "EMI Protection Distance." It is labeled "Draft - August 15, 1994" and was given to Federal Communications Commission (FCC) staff at an inter-agency meeting held at the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) on August 15, 1994. The purpose of the meeting had been to discuss the issue of potential electromagnetic interference to medical devices, and how the FCC and the CDRH might work together to try and resolve problems that might arise with respect to this issue.

The document is a table showing how levels of increasing immunity to (protection from) EMI for medical devices could be correlated with distances from various transmitters of radiofrequency (RF) energy. In other words if one were to maintain the stated distance from a given transmitter and if the medical device in question had the stated level of immunity, then there should not be an EMI problem, at least theoretically.

This table was developed using a mathematical relation that indicates minimum separation distance is proportional to the square root of the power and the inverse of the immunity level. This is explained on the reverse side of the document. Also, there is an explanation of the limitations of the mathematical equation used, and it is stated that the recommended protection distances are approximate. Actual protection distance is affected by antenna efficiency and pattern; multipath reflections; and absorption by objects such as buildings and people. Reflections could increase the protection distances while absorption could decrease them. These levels were calculated using maximum power allowed for the FCC for each respective type of transmitter and only single emitters were used to calculate each distance. Worst-case assumptions were made with respect to the electromagnetic susceptibility of the medical device.

This document was only meant to be a point of discussion. As we understand it, it was not intended to be a precursor to a regulatory action by the FDA. It should be viewed as a draft document to be used for research and analytic purposes only. It is a scientific approach to understanding the problem but should not be taken as a definitive explanation of why EMI might occur to a specific medical device in a given situation. The FCC recognizes these facts and would caution against anyone using it to support actions that would limit use of telecommunications devices in certain environments.

Mr. CONDIT. Thank you. I will yield to Mr. Thomas. If he wants to make his opening statement, he's welcome to do that, or if you have any questions, you're welcome to do that.

Mr. THOMAS. Thank you, Mr. Chairman.

My statement was put in the record and I apologize for being late. I thank you for having this hearing. I'll defer to my associate, Mr. Horn.

But let me, first of all, just say in general that it does seem to me that the private sector, from what I know, is moving on this issue, doing something on this issue to resolve the problem, and I would hope that the industry groups would be given an opportunity, as opposed to additional regulation. God knows we have enough of that.

Just one sort of general question. Press reports, of course, have assigned cellular phone industry and other activities to certain malfunctions. Do you, in your regulatory function, have sort of a risk-benefit approach? In other words, how important is the whole cellular, wireless industry compared to the potential risk involved? Do you use that sort of a risk-benefit, cost-benefit ratio at all?

Mr. STANLEY. Insofar as data is available, certainly. We would like to hope that we bring forth a full record. All too often the record is incomplete and so frequently we have to rely on sort of a general understanding as to the impact. Let me give one example.

Some particular devices for which there have been absolutely no interference complaints used in hospitals have asked the Commission if they could get out from under some of our regulations. They point out that the testing is expensive and prolonged. And in this kind of environment where there are no specific instances of interference and there is a cost to testing being borne by the industry, then we are persuaded generally to get them out from under particular regulations.

So where information is available, either in testimonies of interference complaints or situations or cost of compliance, we very much take that into account.

Mr. THOMAS. Would you mind providing specific instances? It would be a heartening breakthrough of where FCC deregulated something.

Mr. STANLEY. Yes, indeed. Happy to.

Mr. THOMAS. I would be happy to see that.

Mr. STANLEY. Happy to.

[The information can be found in the appendix.]

Mr. STANLEY. I might add: in the medical electronics area, under the Commission regulation, we've had a long series of devices that, because they are shielded themselves and are operated by professional technicians usually in closed environments where the technicians are under complete control of the situation, we have moved in several areas: medical ultrasound, magnetic resonance imaging, a series of devices, area-by-area. Insofar as the hospital environment that they are operating in is generally under the control of professionals, where they can take care of their own interference situation and there is no interference to, say, broadcast services, licensed services, then these are areas we have deregulated; and we would be very happy to provide that information.

Mr. THOMAS. I would appreciate it and I will read your report. I defer to my associate.

Mr. CONDIT. Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman.

Let me first put on another hat which is membership on the Subcommittee on Aviation of Public Works and Transportation. As you know, there have been various allegations about the interference with the airplane electronic equipment by people having various types of electronic devices onboard. Some reports say we can't replicate that damage and it remains a sort of questionable conclusion about the degree of interference.

Has the FCC been involved in any of those studies with the Department of Transportation and the Federal Aviation Administration?

Mr. STANLEY. To my knowledge, we are not directly involved with their analysis. For the environment on an aircraft, the experts on that are the aircraft industry and the FAA itself. We certainly make available any information on the environment, such as would be contributed by FCC licensees, for example, cellular license—cellular consumer or customer. Or an industry that has a device, for example, a CD player or a radio or cassette player.

I think you are correct in characterizing this as an area which at this time, is not well understood as to the direct phenomenology of what exactly is going on. As you can imagine, there is a variety of aircraft situations with passengers carrying different kinds of transmitters. Currently, it appears as though it is fairly widespread practice to limit at least in takeoff and landing most, say, consumer electronics. Cellular radio telephones are prohibited throughout the flights.

Mr. HORN. There is also a Consumer Product Safety Commission. There is a lot of electronic equipment, be it toys or other types of things, consumers buy. Has the FCC been called upon to work with them in any way or do you know of any research they have under way in this area?

Mr. STANLEY. I have no personal knowledge of that particular agency or any of its programs.

Mr. HORN. The thought comes to mind that there are these little sprinkles of endeavors dealing with somewhat of the same problem we are talking about here and should the executive branch perhaps pull that together by an interagency committee of some sort.

I simply raise that notion, Mr. Chairman, as a possibility because there are these prongs out there. I have a series of questions I am going to file for the record with the staff and I'd like you to answer it going from the jurisdiction to some of the things you've already done. It seems to me a lot of that can be handled in writing for the record and not delay the hearing.

[The information can be found in the appendix.]

Mr. HORN. That's all, Mr. Chairman.

Mr. CONDIT. Thank you, Mr. Horn.

Dr. Stanley, thank you very much for being here this morning. We are not shortchanging you. I have a series of questions, too, that I'd like to submit to you in writing, ask for you to answer them in writing.

And once again, the one I would like for you to followup is the document, the protection distance draft and a formal response to that, if you would. But we'll submit those to you.

Thank you very much for being here.

Mr. STANLEY. Happy to respond. Thank you.

[The information can be found in the appendix.]

Mr. CONDIT. We'll take the next panel. Would you please rise. We have a policy of swearing everyone in, please.

[Witnesses sworn.]

Mr. CONDIT. We're going to start with Mr. Swanson.

First of all, let me say we appreciate both of you being here on short notice. We understand that you had to speed up just to get here and we appreciate that very much. And let me say that from my point of view, as chairman of this subcommittee and as a member of the full committee, we think the solution for whatever problems we have—and we're not sure what they are yet—should come from the private sector.

We appreciate your openness and your participation in this hearing and we are going to look to you folks in the future to help us find whatever solution we come up with, if there is a remedy, from this subcommittee to come from the private sector. So I just want to say that so that you clearly understand you are in friendly territory here.

So, Mr. Swanson, you may proceed.

STATEMENTS OF CHARLES SWANSON, VICE PRESIDENT, REGULATORY AFFAIRS, PACING, MEDTRONICS, INC., REPRESENTING THE HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; AND JOHN STUPKA, PRESIDENT AND CHIEF EXECUTIVE OFFICER, SOUTHWESTERN BELL MOBILE SYSTEMS, REPRESENTING THE CELLULAR TELECOMMUNICATIONS INDUSTRY ASSOCIATION

Mr. SWANSON. Thank you. Mr. Chairman, members of the committee, my name is Charles Swanson. I am a vice president with Medtronic, Inc., located in Minneapolis, MN. I am here today on behalf of the Health Industry Manufacturers' Association, a national trade association representing 700 manufacturers of medical devices, in vitro diagnostics and health care information systems with manufacturing facilities in the United States. On behalf of HIMA members, I thank you for this opportunity to testify at the hearing today.

Recent technological advances have improved the performance of wireless communication devices and many medical devices by adding speed, increasing accuracy, permitting the inclusion of new advanced functions, reducing size and increasing portability. The proliferation and portability of these devices have greatly increased the potential for wireless communication and medical devices to come into proximity. And with that increased proximity, there is an increased potential for electromagnetic interference or EMI.

This increased potential has raised concerns regarding the mutual compatibility of medical devices and wireless communications devices. The medical device industry recognizes the serious consequences that EMI can pose to patients and has been working for several years to develop standards for the electromagnetic compatibility [EMC] of medical devices. In addition, individual companies test their devices for EMC and strive to maintain the highest levels of safety for the devices they market.

EMI is the adverse effect of the electromagnetic environment on an electronic device, and one of the more common sources of EMI is radiated emissions. Interference can take the form of impaired function, inhibited function, or even a loss of function. EMI is not limited to medical devices. Early television sets, for example, used to suffer from EMI when airplanes flew overhead and the reception was degraded. In this case, the airplane was not designed to emit electromagnetic radiation but nevertheless did, and the television set was unable to filter out the interference.

EMC, a related term, is the ability of a potential radiator and receiver to function in the same environment without interfering with each other. To use the example of the television set and the airplane, newer television sets are better equipped to filter the radiation received from an airplane so the airplane's passing is virtually unnoticed. The two devices can be described as electromagnetically compatible.

The concept of EMI and EMC are not new to the medical device industry. Fortunately, however, most instances of EMI do not result in adverse effects for patients. In some cases, medical devices can even interfere with each other. Certain devices are themselves designed to emit electromagnetic energy as part of their fundamental operation—electrosurgical units, for example—devices that use radio frequency energy to simultaneously cut and cauterize tissue.

When such devices are activated in proximity to other devices, they may be affected. However, the effects are known, understood and, in most cases, expected. For example, the display on a patient monitor becomes unstable for a few seconds while an electrosurgery unit is operating and then returns to normal immediately after the unit is turned off. It causes no harm since medical personnel expect the phenomenon account for it.

Another example is the interaction between implantable cardiac pacemakers and magnetic resonance equipment, or MRI's. MRI's use electromagnetic energy for patient diagnostics. If the patient also has a pacemaker, its function can be adversely affected by the MRI. When MRI's were originally introduced, the pacemaker industry worked with the medical community to understand these effects on pacemakers, and as a result, the medical community now knows that MRI's should not be used on pacemaker patients.

A less controlled situation arises when a device other than a medical device—for example, cellular phones, hand-held radios, or other wireless communications devices—interferes with the proper operation of a medical device. Such interactions are generally not anticipated. Fortunately, many unrelated chance factors must coincide to create a serious adverse incident initiated by the EMI.

There must be a radio frequency emitter near the medical device. The device must be sensitive to the emitted frequency. The device must be performing a function that can result in a serious adverse effect if interrupted or corrupted. And finally, the radio frequency transmitter must be operating at the same time as the medical device, close enough to the device and for a long enough period of time to interfere with the device's operation. Based on the number of reported device malfunctions, this combination of conditions has in the past been infrequent.

In 1993, the International Electrotechnical Commission [IEC], one of the preeminent international standards-setting bodies, established a collateral standard for electromagnetic compatibility. The principal work in developing this standard was underwritten by the U.S. medical device industry. The standard was developed with the cooperation of many international representatives, including those from the Food and Drug Administration. Work is continuing today to continue to refine that standard further.

We believe that the development of this standard is a major step forward. For the first time, medical device manufacturers have a recognized standard to guide them in the design and testing of their devices, both for emissions and immunity. Although FDA has developed its own requirements beyond the standard for some devices, the agency has recognized that this standard represents a solid basis for assuring electromagnetic compatibility of medical devices under most reasonably anticipated conditions.

In addition, the European Union will soon require minimum levels of EMC for all electrical devices, including medical devices. We are confident that the new IEC standard, FDA's increased interest in EMC, and the European Union requirements will result in a noticeable increase in the EMC performance of new medical devices.

Standards are not a complete solution, however. As technologies evolve, new sources of EMI will arise. When I started with Medtronic back in the mid-1970's, one of the common sources for EMI for cardiac pacemakers came from a new home appliance—microwave ovens. Those problems have been solved. Today, the concern is with EMI from wireless communication devices. Tomorrow, it may be yet another technology.

To minimize the potential for adverse interactions, medical device manufacturers must remain as vigilant for new sources of EMI as they are today. Similarly, manufacturers of radiation emitting products must be sensitive to their potential effects on medical devices.

I'd like to turn now to the issue directly affecting the specific problems on which you sought our comments. Much attention has been drawn to the reports of adverse response of medical devices to the use of cellular phones. These reports have raised concerns of many hospitals to the point that some have banned the use of cellular phones anywhere within their facilities.

It is clear that, under certain circumstances, the use of cellular phones in the vicinity of certain medical devices can affect a medical device, possibly to the detriment of a patient. Generally, the phone must be quite close to a medical device to affect it at all. The effects can be demonstrated and avoided.

The cellular phone is not the only device of concern. The use of wireless communications technology is proliferating quite rapidly. A small sample of the things we expect to see in the next few years includes personal communication devices, which allow the owner to have a single phone number that allows calls to find him or her regardless of location, wireless modems for laptop computers, and the medical device community itself will undoubtedly adopt technologies permitting the wireless transfer of patient information in real time.

In some cases, it may be possible to harden medical devices to make them even more immune to interference from wireless communication devices. For example, for devices that are not connected electrically to the patient, it may be useful to replace a plastic case with a metal case without significantly increasing the cost. In other cases, such hardening may not be possible within currently available technology without compromising essential medical device function.

For example, vital signs monitors widely used in operating rooms, intensive care units, and emergency rooms cannot be made entirely immune to extraneous radio frequency emissions. The leads that connect the patients to the monitors and even the patient act as crude but effective antennas to receive the radio frequency radiation. Thus, there is a limit to the degree of immunity that manufacturers can build into such devices.

Another example is provided by the implantable pacemaker. These devices are implanted in the body to regulate the heartbeat in patients whose bodies cannot adequately handle that function. Many thousands of people have been able to lead normal, active lives as a result of the functioning of their implanted pacemakers. All modern pacemakers function by detecting very small electrical signals within the heart. As a result, they cannot be made immune to EMI, particularly that which falls within the normal spectrum of the cardiac activity. That is, the pacemaker must be sensitive to signals within the frequency spectrum of the heart.

Certain new cellular technologies require that a phone be polled meaning that the phone is signaled electronically in response to the cell by broadcasting a signal, much as if it were being used. This permits the cell system to know where to route a call for that particular phone.

Many of those phones can be folded and stored in a shirt or jacket pocket within inches of an implanted pacemaker. At such short range, the pacemaker may sense the signals generated by the phone—as the phone broadcasts back to the cell and the pacemaker's operation may be affected, potentially affecting the well-being of the patient. However, in use, held next to the ear, the phone is farther removed from the pacemaker and the potential for interference with normal pacemaker function is greatly reduced.

Let me assure the subcommittee that these medical devices are safe; 24 hours a day, every day of the year, many thousands of people lead active and productive lives because of their implanted pacemakers and many thousands of hospital patients are monitored by advanced equipment. These patients are real people; they are your relatives and mine. Each of us may, and likely will, at some day be patients ourselves.

This equipment can save countless lives and the instances of electromagnetic interference are infrequent. We are concerned here with relatively infrequent events and our interest is ensuring that the problem of EMI is minimized to the greatest extent possible.

As I mentioned previously, there are several approaches to alleviate these problems, each of which must be carefully considered, weighing the benefits and the costs: First, ban the use of cellular phones throughout hospitals; second, limit the use of cellular phones and other wireless communications within hospitals, possibly prohibiting their use within critical care areas and other potentially sensitive areas; third, design new medical devices to increase their resistance to electromagnetic radiation from wireless communications devices when possible; fourth, utilize standards to establish EMC test requirements and to characterize medical device performance and develop user awareness of potential for interference; and fifth, establish a high level of cooperation between the two industries to ensure that medical devices and wireless communications devices can operate compatibly in the future.

We believe that, No. 1, although easy for a hospital, is extreme, there is no reason to prevent hospital staff or visitors, for that matter, from utilizing this new beneficial communications tool. However, at the same time, we must emphasize that medical device technology is well established. It is there only to restore and to ensure patient health.

Cellular communications are a relatively new and extremely beneficial technology. However, because they are new and because their operation depends on the emission of radiation that can negatively affect the operation of these critical medical devices that are so vital to the well being of the populace, we believe they must bear a significant part of the burden for alleviating the resultant problems.

This is not to say that we believe that device manufacturers have no responsibility in the matter. Device manufacturers should, and in most cases do, build devices that are reasonably immune to EMI. Newer devices designed to satisfy EMC standards should further improve immunity. I say reasonably immune because it is neither technically nor economically feasible to build medical devices that are totally immune.

In some cases, total immunity would inhibit the device function; in other cases, it would be too cumbersome and complex to be used successfully. Finally, total immunity comes at an extremely high price, something our already taxed health care system would have difficulty with.

This is not a problem solely with communications systems operators. Nor is it a problem only of medical device manufacturers. The problem is jointly held and will be solved ultimately by joint effort. We believe that the development of viable solutions for the compatible use of medical devices and wireless communications devices is the obligation of both industries. The very fact that about 500 people attended a very successful conference on electromagnetic compatibility that was held in Dallas last week and sponsored by both the Cellular Telecommunications Industry Association and the Health Industry Manufacturer Association provides ample evidence to support this belief.

Speaking on behalf of the pacemaker industry, I'd like to report one of the outcomes of that conference. We have agreed to work with CTIA, the medical community, and FDA to develop a test protocol to evaluate the effects of cellular phones on pacemaker operation. These tests will be conducted at the University of Oklahoma Center for Study of Wireless Electromagnetic Compatibility, and I fully expect that this will assist both industries in improving electromagnetic compatibility.

We expect that a modified combination of options two, three, and four will lead to the most practical solution with option five providing the most solid basis for a long-term solution. In some cases, medical devices can be redesigned to be immune to the signals broadcast by wireless communication devices. In other cases, this simply will not be feasible.

In some rare instances, it may be necessary to ban the use of cellar phones or similar devices throughout the hospital, for example, if they were to interfere with other vital hospital systems, like fire protection. In most cases, limiting the use of cellular phones in critical areas of the hospital will be sufficient. For devices like pacemakers used outside of the hospital environment, these alternatives are not available. Where immunity to EMI cannot be designed into the device, the user must be informed of those sources which can affect the operation of their medical device.

Less than 2 weeks ago, the Canadian Health Protection Branch, the Canadian equivalent of FDA, convened a meeting of EMC experts from both industry, academia, hospitals, and the Canadian FCC equivalent. The approach I have advocated is consistent with the unanimous conclusions drawn by that group, adopting the approach that wireless communications devices should be managed within hospitals rather than banned.

I must emphasize, however, that the limitations on the use of wireless communications devices in hospitals is a short-term solution to only part of the problem. In the long-term, the wireless communications industry and the medical device industry must maintain close contact. We must each be aware of the other's innovations and advances and we must work together to ensure that our equipment designs account for mutual compatibility.

We must also recognize that total compatibility will not always be achievable, and when we fail to reach that goal, we must compromise. In some cases, that may mean limits on the use of communications devices in hospitals; in others, it may mean limiting the use of certain devices to shielded locations within hospitals. For both, it may mean communication to our respective users of the potential consequences for medical device operation. In either case, the watchword must be cooperation to ensure that two fields of technology with extraordinary potential for benefiting society provide the greatest good for the greatest number.

Thank you very much.

Mr. CONDIT. Thank you, Mr. Swanson.

[The prepared statement of Mr. Swanson follows:]

Mr. Chairman, members of the committee, my name is Charles H. Swanson, Vice-President, Medtronic, Inc., Minneapolis, Minnesota. I am here today on behalf of the Health Industry Manufacturers Association, a national trade association representing more than 700 manufacturers of medical devices, in vitro diagnostics, and health care information systems with manufacturing facilities in the United States. On behalf of HIMA's members, I thank you for this opportunity to testify at today's hearing.

Background

Recent technological advances have improved the performance of wireless communications devices and many medical devices by adding speed, increasing accuracy, permitting the inclusion of new, advanced functions, reducing size, and increasing portability. The proliferation and portability of these devices have greatly increased the potential for wireless communications and medical devices to come into proximity. And with that increased proximity, there is an increased possibility of electromagnetic interference (EMI). This increased potential has raised concerns regarding the mutual compatibility of medical devices and wireless communications devices.

The medical device industry recognizes the serious consequences EMI can pose to patients and has been working for several years to develop standards for the electromagnetic compatibility (EMC) of medical devices. In addition, individual companies test their devices for EMC and strive to maintain the highest levels of safety for the devices they market.

EMI is the adverse effect of the electromagnetic environment on an electronic device. One of the more common sources of EMI is radiated emissions (radio waves). Interference can take the form of impaired or inhibited function or even loss of function. EMI is not limited to medical devices. Early television sets used to suffer EMI when airplanes flew overhead and reception was severely degraded. In this case, the airplane was not designed to emit electromagnetic radiation, but nevertheless did, and the television set was unable to filter out the interference.

EMC, a related term, is the ability of a potential radiator and receiver to function in the same environment without interfering with each other. To use the example of the television set and the airplane, newer television sets are better equipped to filter the radiation received from an airplane so the airplane's passing goes essentially unnoticed. The two devices can be described as electromagnetically compatible.

The concepts of EMI and EMC are not new to the medical device industry. Fortunately, however, most instances of EMI do not result in adverse effects on patients. In some cases, medical devices can even interfere with each other. Certain devices are themselves designed to emit electromagnetic energy as part of their fundamental modes of operation, e.g., electrosurgery units, devices that use radio frequency energy to simultaneously cut and cauterize. When such devices are activated in proximity to other devices, the other devices may be affected. However, the effects are known, understood, and, most important, expected. For example, the display on a patient monitor becomes unstable for a few seconds while an electrosurgery unit is operating and then returns immediately to normal when the electrosurgery unit is turned off. It causes no harm since the medical personnel expect the phenomenon and account for it.

Another example is the interaction between implantable cardiac pacemakers and magnetic resonance equipment (MRI). MRIs use electromagnetic energy for patient diagnostics. If the patient also has a pacemaker, its function can be adversely affected by the MRI. When MRIs were originally introduced, the pacemaker industry worked with the medical community to understand their effects on pacemakers. As a result, the medical community knows that MRIs should not be used on pacemaker patients.

A less controlled situation arises when a device other than a medical device, e.g., cellular phone, hand-held radio, or other wireless communications device, interferes with the proper operation of a medical device. Such interactions are generally not anticipated. Fortunately, many unrelated chance factors must coincide to create a serious adverse incident initiated by EMI. There must be a radio frequency emitter near the medical device. The device must be sensitive to the emitted frequency. The device must be performing a function that can result in a serious adverse event if it is interrupted or corrupted. Finally, the radio frequency transmitter must be operating at the same time as the medical device, close enough to the device, and for a long enough time to interfere with the device's operation. Based on the number of reported device malfunctions, this combination of conditions has in the past occurred infrequently.

In 1993, the International Electrotechnical Commission (IEC), one of the preeminent international standards-setting bodies, published collateral standard IEC 601-1-2: Electromagnetic Compatibility - Requirements and Tests. The principal work in developing this standard was underwritten by the United States medical device industry. The standard was developed with the cooperation of many international representatives, including representatives from the Food and Drug Administration (FDA). Work is continuing today to refine this standard further.

We believe that the development of this standard is a major step forward. For the first time, medical device manufacturers have a recognized standard to guide them in the design and testing of their devices for both emissions and sensitivity (immunity). Although the FDA has developed its own requirements beyond the standard, the Agency has recognized that this standard represents a solid basis for assuring the electromagnetic compatibility of medical devices under most reasonably anticipated conditions.

In addition, the European Union will soon require minimum levels of EMC for all electrical devices, including medical devices (most likely IEC 601-1-2). We are confident that the new IEC standard, FDA's increased interest in EMC, and the European Union requirements will result in a noticeable increase in the EMC performance of new medical devices.

Standards are not a complete solution, however. As technologies evolve, new sources of EMI will arise. When I started with Medtronic in the mid-1970s, one of the common sources of EMI for cardiac pacemakers came from a new home appliance, the microwave oven. These problems have been solved. Today the concern is with EMI from wireless communications devices. Tomorrow, it may be yet another new technology. To minimize the potential for adverse interactions, medical device manufacturers must remain as vigilant for new sources of EMI as they are today. Similarly, manufacturers of radiation emitting products must be sensitive to their potential effects on medical devices.

Current Issues

I would now like to address more directly the specific problems on which you have sought our comments. Much attention has been drawn to reports of adverse response of medical devices to the use of cellular telephones. These reports have raised the concerns of many hospitals to the point that some have banned the use of cellular telephones anywhere within their facilities.

It is clear that under certain circumstances the use of a cellular telephone in the vicinity of certain medical devices can affect a medical device, possibly to the detriment of a patient. Generally, the phone must be quite close to a medical device to affect it at all. The effects can be demonstrated and avoided. The cellular phone is not the only device of concern. The use of wireless communications technology is proliferating quite rapidly. A small sample of the things we expect to see in the next few years includes personal communications devices (portable telephones that permit the owner to have a single phone number that allows calls to find him or her regardless of location), wireless modems for laptop computers, and the medical device community itself will undoubtedly adopt technologies permitting the wireless transfer of patient information in real time.

In some cases it may be possible to "harden" medical devices to make them even more immune to interference from wireless communications devices. For example, for devices that are not connected electrically to the patient (i.e., via leads), it may be useful to replace a plastic case with a metal case without significantly increasing the cost. In other cases, such hardening may not be possible with currently available technology without compromising essential medical device function. For example, vital signs monitoring equipment, used widely in operating rooms, intensive care units, and emergency rooms to keep track of the current status of patients, cannot be made entirely immune to extraneous radio frequency emissions. The leads that connect the patient to the monitor and even the patient act as crude but effective antennae to receive the radio frequency radiation. Thus, there is a limit on the degree of immunity that manufacturers can build into such devices.

Another example is provided by the implantable pacemaker. These devices are implanted in the body to regulate the heartbeat in patients whose own bodies cannot adequately handle that function. Many thousands of people have been able to lead normal, active lives as a result of the functioning of their implanted pacemakers. All modern pacemakers function by detecting very small electrical signals within the heart. As a result, they cannot be made immune to EMI, particularly that which falls within the normal spectrum of cardiac activity That is, the pacemaker must be sensitive to signals within the frequency spectrum of the heart.

Certain new cellular technologies require that the phones be "polled," meaning that the phone is signalled electronically and responds to the cell by broadcasting a signal much as if it were being used. This permits the cell system to know where to route a call for that particular phone. Many of these phones can be folded and stored in a shirt or jacket pocket within inches of an implanted pacemaker. At such short range, the pacemaker may "sense" the signal generated when the phone broadcasts back to the cell and the pacemaker may change the way it sends out its own pulses, potentially affecting the well being of the patient. However, in use, held next to the ear, the phone is farther removed from the pacemaker and the potential for interference with normal pacemaker function is greatly reduced.

Let me assure the Subcommittee that these medical devices are safe. Twenty-four hours a day, every day of the year, many thousands of people lead active and productive lives with implantable pacemakers and many thousands of hospital patients are monitored by advanced equipment. These patients are real people; they are your relatives and mine. Each of us may, and likely will, spend time as a patient. This equipment saves countless lives and the instances of electromagnetic interference are infrequent. We are concerned here with relatively rare events. Our interest is in ensuring that the probability of EMI is minimized to the greatest extent possible.

Suggested Solutions

As I mentioned previously, there are several approaches to alleviating these problems each of which needs to be carefully considered, weighing the benefits and the costs.

1. Ban the use of cellular telephones throughout hospitals.

2. Limit the use of cellular phones and other wireless communications devices within hospitals, possibly prohibiting their use within critical care areas and other potentially sensitive areas.

3. Design new medical devices to increase their resistance to electromagnetic radiation from wireless communications devices when possible.

4. Utilize standards to establish EMC test requirements to characterize medical device performance and develop user awareness of the potential for interference.

5. Establish a high level of cooperation between the two industries to ensure that medical devices and wireless communications devices can operate compatibly in the future.

We believe that number one, although easy for the hospital, is extreme. There is no reason to prevent the hospital staff or visitors, for that matter, from utilizing a useful new communications tool. However, at the same time, we must emphasize that medical technology is well established. It exists only to restore and ensure patient health, often providing the only means by which a person can stay alive. Cellular communications are a relatively new and extremely beneficial technology. However, because they are new and because their operation depends on the emission of the radiation that can negatively affect the operation of the medical devices that are so vital to the well being of the populace, we believe that they must bear a significant part of the burden for alleviating any resultant problems.

This is not to say that we believe that device manufacturers have no responsibility in the matter. Device manufacturers should, and in most cases do, build devices that are reasonably immune to EMI. Newer devices designed to satisfy EMC standards should further improve immunity. I say reasonably immune because it is neither technically nor economically feasible to build medical devices that are totally immune. In some cases, a totally immune device simply would not work. In others, it could be too cumbersome or complex to be used successfully. Finally, total immunity comes at an extremely high price, something our already taxed health care delivery system would have difficulty handling.

This is not a problem solely of communications system operators. Nor is it a problem only of medical devices manufacturers. The problem is jointly held and will be solved ultimately by a joint effort. We believe that the development of viable solutions for the compatible use of medical devices and wireless communications devices is the obligation of both industries. The very fact that about 500 people attended the highly successful Electromagnetic Compatibility Challenge - Medical & Wireless Device Interaction Conference that was held in Dallas last week and sponsored by both the Cellular Telecommunications Industry Association and HIMA provides ample evidence to support that belief.

We expect that a modified combination of options 2, 3, and 4 will lead to the most practical solution, with option 5 providing the most solid basis for a long-term solution. In some cases, medical devices can be redesigned to be more immune to the signals broadcast by wireless communications devices. In other cases, this will simply not be feasible. In some rare instances, it may be necessary even to ban the use of cellular phones or similar devices throughout a hospital. (If, for example, the phones affect some other vital hospital system like fire protection.) In most cases, limiting the use of cellular phones in critical areas of the hospital will be sufficient. For devices like pacemakers used outside the hospital environment, these alternatives are not available. Where immunity to EMI cannot be designed into the devices, the user must be informed of those sources of EMI which can affect the operation of their medical device.

Less than two weeks ago, the Canadian Health Protection Branch, the Canadian equivalent of the FDA, convened a meeting of EMC experts from both industries, academia, hospitals, and the Canadian FCC equivalent. The approaches I have advocated are consonant with the unanimous conclusions drawn by that group, adopting the approach that wireless communications device use should be managed within hospitals rather than banned.

I must emphasize, however, that limitations on the use of wireless communications devices in hospitals is a short-term solution to only part of the problem. In the long-term, the wireless communications industry and the medical device industry must maintain very close contact. We must each be aware of the other's innovations and advances, and we must work together to ensure that our equipment designs account for mutual compatibility.

We must also recognize that total compatibility will not always be achievable, and when we fail to reach that goal, we must compromise. In some cases that may mean limits on the use of communications devices in hospitals; in others it may mean limiting the use of certain devices to shielded locations within the hospital. For both, it may mean communication to our respective users of potential consequences for medical device operation. In either case, the watchword must be cooperation to ensure that two fields of technology with extraordinary potential for benefiting society provide the greatest good for the greatest number.

Mr. CONDIT. Mr. Stupka.

Mr. STUPKA. Thank you.

My name is John Stupka and I'm president and chief executive officer of Southwestern Bell Mobile Systems. I also have the pleasure of serving this year as the chairman of CTIA, which is the association that represents the wireless industry within the United States. I would like to thank you, Mr. Chairman, and the committee members, for being here and your interest in this issue.

My goal today might be called the EMC challenge, communications challenge. I'll be attempting to explain how we are aggressively working as industries to address this issue and yet, at the same time, put the EMC issue in perspective. This may be indeed harder than starting a compatibility program. I think you will find that after I quantify the EMC issues for 1994, I'll be able to describe a series of initiatives that have been, many of them triggered by the wireless industry, designed to step up, to address the interaction issues.

After I explain the magnitude of the problems today and the intensity of our actions, you and your committee may perceive a mismatch. If it is truly a mouse, why attack it with an elephant gun? If the problem is so small, why is the effort of the wireless industry so large? This is because the wireless industry intends over time to lend its full force of its mobility, flexibility, and cost-effectiveness to the health care issues of the United States. If we meet the EMC challenge today with intensity, we clear the path for the future.

Please keep this in mind as I go through my remarks. The problem is relatively small today but the issue is big and addressable. After you hear our responses to these emerging issues, I believe that you will question neither our intensity or our sincerity.

Can I have chart 1, please.

It was referenced that we finished a seminar on this issue in Dallas the last week on Thursday and Friday. And the FDA shared with us that they have had 97,000 problem reports concerning medical equipment in the last 12 months. Of these 97,000 reports, 48 of them, or 0.05 percent, were related to the EMC issues. Some of the reports attributed to other causes are unknown may have had EMC components. I think you can see we are dealing with a relatively small problem.

Chart 2, please.

The direct focus on EMC issues is available from FDA data. This chart represents about 100 reports on EMC that have been gathered by the FDA since 1979. Only three of these reports deal with cellular phones, and two of the three are anecdotal. The fact is that even though cellular phones are what I call a majority device, there are a lot of them out there, they are cited in only a minority of cases. But that shouldn't be unanticipated. Portable cellular devices are much lower power than other wireless units. The maximum affected radiated power for cellular is 0.6 of a watt maximum. Most other devices are significantly higher.

While I am attempting to put these things into perspective, I feel compelled to correct this subcommittee's letter to the GAO. The letter referred to press reports of an FDA study. The letter stated that "at least five deaths have been tied to cellular/EMI problems." The letter further states that there are perhaps as many as 100 pending cases in which EMI from cellular phones caused medical devices to fail or malfunction. These allegations are in error. There have been no EMC-related cellular deaths and, just as described, there are precious few reports of cellular-related EMC.

But I want to share with the subcommittee that this does not mean the wireless industry is insensitive to the EMC issue. Far from it. We believe, as the U.S. health initiative progresses, wireless will play an increasing role. Managing interaction will be a key. It is better to start now when the environment is simpler. For instance, immediately learning of the EMC concern, the wireless industry wrote the affected manufacturers urging closer cooperation to eliminate this issue.

In addition, the wireless industry provided the seed capital to establish the Center for Wireless Compatibility at the University of Oklahoma. Utilizing the Nation's most advanced technical facilities, the center will provide a U.L.-like laboratory facility for the establishment of standards and the testing of products to ensure compatibility.

As you know, the center last week held a 2-day conference attended by over 400 health care and wireless specialists to address the specific issue of EMC in the medical environment. At that conference, we heard from the medical community how wireless telecommunications are an essential component of improved health care at lower cost to the patients. One hospital informed us that 67 percent of its staff reported improvements in the quality of health care as a result of using wireless. This kind of finding makes the assurance of electromagnetic compatibility all the more important to all of us.

There was universal agreement at the conference that there are two principal solutions to the EMC challenge. First, minimize the power from the wireless unit; and second, reasonable immunity from the medical devices. The cellular industry is predicated on successfully achieving the former. The latter is a matter of cooperation with the medical device community.

Chart 3, please.

As this chart illustrates, there are multiple sources of RF operating in the medical environment. These sources range from 5 watt walkie-talkie units commonly used by hospital security and maintenance personnel, as well as ambulances and other public safety personnel, to video games being used by children of patients and patients themselves. As a result of FCC regulation, portable cellular phones operate at a maximum power output of 0.6 of a watt.

Chart 4, Mike.

While the maximum power of a portable phone is 0.6, the units are designed to afford operating at peak power. In fact, there are six power steps on a portable phone ranging all the way down to six one-thousands of a watt. Cellular systems are designed to operate at the lowest possible power level in order to, No. 1, preserve their battery life, No. 2, to improve the quality of service for others.

In a recent test in my home system of Dallas, for instance, we found that the portable units operated at the full 0.6 of a watt only 5 percent of the time.

Finally, let me—permit me to graphically present both components of the EMC issue: the level of emitted power and the role of distance in immunity.

Ours is a talkie.

Narrator: At a distance from and immunity of the other device. These factors are illustrated with this typical computer monitor. Some devices, such as this cellular phone, operating at a maximum 0.6 of a watt, have no impact on the monitor's operation. To illustrate the impact of signal power, a 5-watt walkie-talkie is held next to the monitor.

You can see the results. Even at this increased power, however, immunization shielding eliminates the interference. The shielding here is grocery store aluminum foil. Real life shielding is not always as simple as aluminum foil, devices have multiple points of potential signal entry, such as connectors, wires, or even the human body acting as an antenna. This demonstration illustrates the interplay of the two components of electromagnetic compatibility, the power level of the emitting source and the distance from and immunity of electronic device. The solution isn't as simple as tin foil. But you have got two communities interested in solving this.

The EMC should not be blown out of proportion when the Federal Government's own numbers show that it is currently at a very low level. Just as importantly, however, the issue cannot be ignored as we move forward to this wireless century. The EMC challenge for the wireless industry, the medical industry, and the Government is a true challenge. The solution lies in all three parties. I cannot speak for the others, but I can assure you that the wireless industry's modus operandi is to reduce its power to the lowest level, thus mitigating interference.

Furthermore, I am proud that the wireless industry has taken an active lead in creating a technical center to facilitate compatibility activities for all parties to address this challenge. I pledge to you our cooperation.

Thank you.

[The prepared statement of Mr. Stupka follows:]

Mr. Chairman and Distinguished Members of the Subcommittee

My name is John Stupka, and I am here today as Chairman of the Board of Directors for CTIA, the Cellular Telecommunications Industry Association. CTIA is the trade association for the wireless telecommunications industry, representing over 150 member companies that provide cellular and Enhanced Specialized Mobile Radio services, manufacturers of wireless equipment and other professionals interested in the wireless industry. As a member of CTIA, I am also the President and CEO of Southwestern Bell Mobile Systems, headquartered in Dallas, Texas. Southwestern Bell Mobile Systems is one of the five largest cellular carriers in the United States with 55 cellular markets operating in ten states, and providing service to major cities from Chicago in the north, to Dallas in the south and Boston in the east. You are probably most familiar with our business in the D.C area. Southwestern Bell Mobile Systems, providing service under the marketing name of Cellular One, is one of the two cellular carriers serving the Washington D.C. market.

Mr. Chairman, CTIA appreciates the opportunity to testify at this morning's hearing to help shed light on the issue of electromagnetic interference with medical devices. We hope that today's hearing will help assure Congress that the involved industries are collectively -- and with the government -- addressing this important matter.

Your hearing could not have been more timely. Only last Friday 400 participants from the wireless, health care and medical device industries, as well as the government agencies with an interest in this area completed a two-day seminar on the EMC between wireless and medical devices. Planning for this seminar began last winter. The seminar was sponsored by the Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma with support from the Health Industry Manufacturers Association and CTIA. Its purpose was to have experts share their insight and experience on the changing aspects of wireless and medical devices, and provide a forum for coordinating industry efforts to address compatibility issues. In the words of Robert Galvin, Chairman of the Executive Committee at Motorola, this meeting was "An Act of Responsibility."

I think those in attendance would agree with the statement from your invitation to this hearing that an understanding of electromagnetic interaction is essential to achieving electromagnetic compatibility solutions.

1. EMC is a broad challenge: emissions come from many sources and there are multiple devices with insufficient immunity. Responsible action rests with all parties involved.

Today's hearing is centered on medical devices, although the electromagnetic challenge we face is much broader. Let me put the broad-based EMC issue in perspective. In the period September, 1993 to September, 1994 the FDA reports having received 96,781 problem reports. Of this number, 48 -- that's five one hundredths of one percent --were related to EMC of all kinds. See Figure 1

Media accounts that triggered the Subcommittee's request for a General Accounting Office report were based on Food and Drug Administration (FDA) reports chronicling over 100 instances

Problem Reports Received

September 1993 through August 1994

Death	1,762
Serious injury	75,080
User error	106
Breast implant problems	46,733
EMI incidents	48
Total	96,781

Source: Dr. Jeffery L. Silberberg, FDA,
Presented at the Electromagnetic Capability Challenge, Dallas, Texas

Figure 1

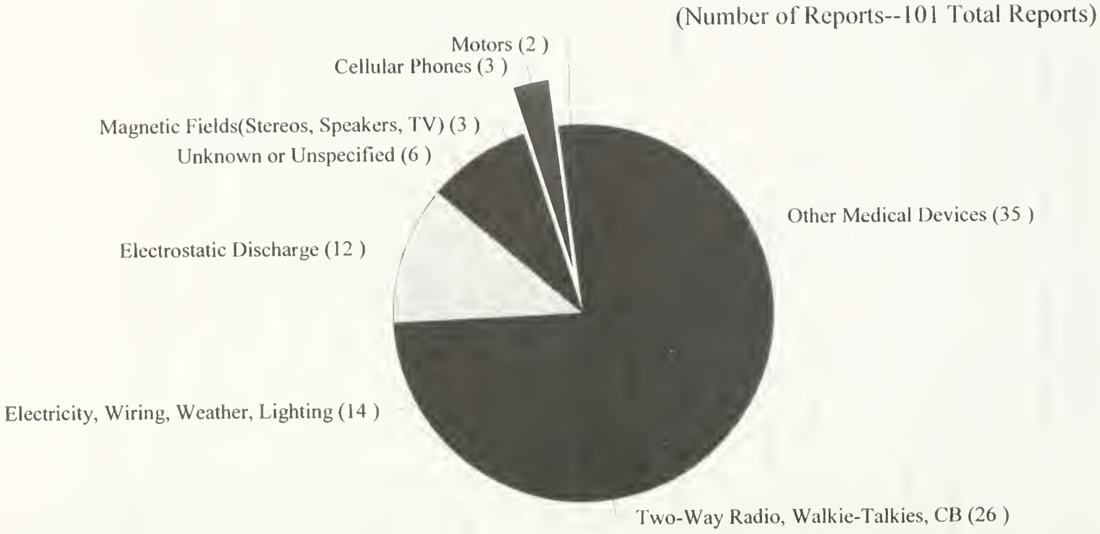
of interference to medical devices filed with the FDA since 1979. These were set forth in an article by Jeffrey Silberberg of the FDA Office of Science and Technology of the Center for Devices and Radiological Health in the publication *Compliance Engineering.* That article concludes with individual descriptions of the causes of the interference. Of the 101 instances of incompatibility in the Silberberg article, cellular is mentioned only three times, two of which are anecdotal. See Figure 2

There has also been a misunderstanding of this issue in the Subcommittee's request to GAO. That letter mistakenly stated mistakenly stated that:

> "According to recent reports in the *Wall Street Journal* and *Communications Daily,* at least five deaths have been tied to cellular/EMI problems, and perhaps as many as 100 pending cases exist in which EMI from cellular telephones caused medical devices to fail or malfunction."

Neither the *Wall Street Journal* nor *Communications Daily* cited cellular phones as the cause of any death. Nowhere is there a record of "as many as 100 pending cases" resulting from cellular telephones. *Communications Daily* stated on page 2 of its June 16 issue, "At least five deaths have been tied to EMI problem, according to FDA records. " The article goes on to point out that EMI comes from many sources including a variety of radio transmitters, and from other medical devices as well. The only fatality discussed in detail in the *Wall Street Journal* article of June 15 was a case in which a 93-year-old heart attack victim died on the way to the hospital. The article stated that the heart monitoring machine shut down when the technicians turned on the ambulance radio transmitter.

Sources of Reported Electromagnetic Interference with Medical Devices



Source: FDA Database

Figure 2

An examination of the FDA information indicates that among the sources of interference to medical equipment are: other medical devices and monitors (the single largest source), AM and FM radios, televisions, electric power lines, pagers, CB and amateur radios, police radios, firefighter radios, ambulance radios, taxi radios, video games, video recorders, walkie-talkies, battery packs, two-way transmitters, personal computers, wireless modems, cordless, cellular and landline phones, garage door openers, baby monitors, telemetry systems, magnetic fields and disturbances, and electrostatic discharges from blankets and people walking. See Figure 3

This information underscores the fact that electromagnetic compatibility concerns are not limited solely or primarily to the cellular industry. Electromagnetic compatibility issues affect every device that contains computing power or that is controlled by computers. While most of these devices co-exist today, the proliferation of computing devices and radio devices will continue to increase the challenge of co-existence.

To anyone involved in the medical devices or communications communities this information is not surprising. Technological advances have always required re-evaluation of old ways of doing things. Technology has changed our world -- for the better -- and it's changing faster every day.

This revolution is being caused by affordable electronic and digital circuits. While few people in the mass markets ever use their full names -- "digital signal processors" (DSPs) or

Sources of Interaction With Electronic Medical Devices

- Other medical devices and monitors
- AM and FM radios
- Televisions
- Electric power lines
- Pagers
- CB and amateur radios
- Police radios
- Firefighter radios
- Ambulance radios
- Taxi radios
- Video games
- Video recorders
- Walkie-talkies
- Battery packs
- Two-way transmitters
- Personal computers
- Wireless modems
- Cordless, cellular and landline phones
- Garage door openers
- Baby monitors
- Telemetry systems
- Magnetic fields and disturbances
- Electrostatic discharges from blankets and people walking

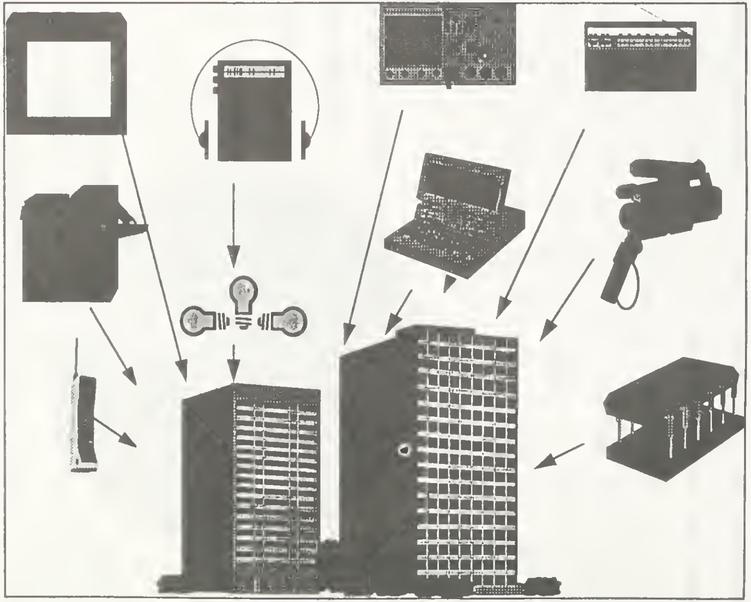


Figure 3

"microprocessor units" (MPUs) -- they are everywhere and they will be the driving force for the future.

From CD players and "Gameboys" to laptop computers and imaging machines, MPUs and DSPs are at work. Devices that have been analog forever are moving to DSPs for speed, reliability and accuracy. From the change mechanism on your office vending machine to the lab equipment that analyzes your blood, MPUs and DSPs are on duty. To handle 30 million instructions per second used to take a mainframe computer, now it's a $20 chip. Custom chips or "ASICs" of the past took many months and millions in R&D to create, now they come quickly and affordably. The message here is simply that the proliferation of digital circuitry is here to stay, and all MPUs and DSPs both transmit and receive signals at some level.

With this exponential growth in devices incorporating digital circuitry, electromagnetic compatibility is the responsibility of all sectors involved in the digital explosion. There is no room for an "it's not my problem" position from any party.

2. Wireless is an essential component of improved health care.

Within the health care community, this technical revolution has tremendous consequences. Not only will health care providers and medical facilities have increased reliability, accuracy and speed in their medical devices, but also access to wireless services and devices to complement and extend health care delivery. Health care providers can get instant access to all kinds of patient and diagnostic information remotely. Video services will become affordable. Inventories can be checked and monitored wirelessly. Charts will never be lost.

This is not the distant future. These wireless tools are coming and coming quickly. In a presentation at last week's seminar by an administrator at St. Agnes Hospital in Fresno, California, a survey of patients, medical and caregiving personnel noted a 67 percent improvement in quality of health care since a similar low-powered two-way telecommunications system was installed at the hospital. Other hospitals have installed similar low-powered two-way wireless systems which enable doctors, nurses and hospital staff to provide better service at reduced cost.

These advances are not limited to improved systems within hospital facilities. The increased reliability and decreased size of medical devices made possible by MPUs are allowing health care technologies to move outside the hospital and into homes and other remote facilities. As an example, consider the case of a woman experiencing a problem pregnancy that requires constant monitoring. Older technologies required that the woman be confined in a hospital bed, connected to the wall or the monitors themselves. With improved technology and wireless telecommunications that same woman can be monitored from home: Not only is such wireless monitoring less expensive, not only does it free up a hospital bed for the truly ill -- it improves the quality of life of the patient who is no longer trapped in a hospital.

Technological advances can bring tremendous benefit to health care services, providers and patients. All these tools should be able to co-exist. Compatibility can be achieved through focused examination and diligent application of standards. Jeffrey Silberberg of the FDA stated this well, at the EMC Compatibility Forum, "Many EMI problems could be prevented using existing design techniques, standards and test methods."

3. Lower power and increased distance contribute to electromagnetic compatibility.

It is widely acknowledged that there are two contributors to EMC solutions: lower power from emitting devices and increased distance from the source of the emission. Cellular systems have historically moved to lower and lower power levels. This is necessary to provide improved capabilities to subscriber units -- such as longer battery life -- and to increase the capacity of the systems. To increase capacity, cellular systems have added more cells and decreased the radius and power of the cells. This not only allows cellular systems to re-use the frequencies more often and increase the number of users on the system, it also lowers the cell's power output. The entire history of the wireless industry leads to an assumption of continuing decreases in power emitted either from base stations or hand held units.

Thus, the cellular carriers are addressing the first solution component -- lower power. The second solution component, distance, can be dealt with either by increasing the physical distance from the emitting device or by increasing the medical device's immunity to emitters through shielding or design. There are currently no mandatory RF immunity standards for medical devices except for apnea monitors and power wheel chairs. Just as the wireless industry is working to reduce power, so must the medical device community work to increase immunity. It would be a tragedy to keep the benefits of wireless technology out of the health care system because medical equipment cannot coexist with low power wireless units.

4. **Industry and government, working together, continue to evolve standards for compatibility.**

RF immunity levels, design techniques and emission characteristics are among the many aspects of the EMC equation that are being discussed and addressed by the affected industries. The Electromagnetic Compatibility Challenge Forum I have cited in my testimony is only the most recent activity.

I began by recounting this Forum, held in Dallas last week. Let me now provide more detail on the sponsoring Center and on the other efforts and activities underway to address the issue of electromagnetic compatibility.

The Center for Electromagnetic Capability was established in early 1994 with seed money from the wireless industry. The Center is now seeking support from the manufacturers of medical and medical testing devices.

The goal of the Center is to independently investigate issues related to the electromagnetic compatibility of electronic equipment with wireless devices. The Center will include capabilities to provide education to industry and wireless users, a clearinghouse to monitor the state of the art in trade organizations and standards committees, and research/test facilities for products related to the wireless industry. The Center is located on the campus of the University of Oklahoma and is managed by the School of Industrial Engineering with a strong research partnership with the School of Electrical Engineering. The Center also has access to AT&T's 30 acre, $5 million dollar Open Are Test Site (OATS) EMC Lab in Oklahoma City, the premier facility of its kind in the nation.

The Center has an industrial advisory board and a group of founding companies that provided the initial startup funds. Companies may participate in a variety of ways by becoming sponsors of the center and/or users of the services offered by the center. The strategy is to include a variety of companies from the wireless, medical, automotive and aviation industries. One of the Center's first research projects is to analyze cardiac pacemaker and defibrillator compatibility with the wireless technologies proposed for operation in North America. CTIA members stand behind the efforts of the Center, but this is not the only effort underway to address electromagnetic compatibility issues.

Canadian carriers, researchers, hospitals, and government representatives have been exploring EMC issues since last summer. A major effort is underway through McGill University to develop strategies that will permit the side by side operation of communications devices and medical equipment. In a roundtable discussion held September 22 and 23, representatives of Health Canada, Industry Canada, and medical and wireless service providers determined that managed compatibility is the best way to proceed.

Underwriters Laboratories (UL) already includes compatibility testing in programs for some electronic devices. Cellular industry representatives have had initial discussions with UL representatives regarding initiating a program for expanding compatibility testing to medical and other electronics equipment based on standards developed by the scientific community.

A number of standards bodies and professional societies also address these issues. The list includes the Institute of Electrical and Electronics Engineers (IEEE) Electromagnetic Compatibility Society, the American National Standards Institute (ANSI) Standards Committee 63 Working Group on Medical Devices, the Society of Automotive Engineers EMI Standards Committee, the Bioelectromagnetics Society (BEMS) and the Association for the Advancement of Medical Instrumentation (AAMI). Membership in these organizations includes academic, government and industry scientists and engineers who specialize in electromagnetic interaction. The cellular industry will work with these organizations on an on-going basis regarding electromagnetic compatibility.

5. **How do we meet the electromagnetic compatibility challenge?**

The answer is to work together and to accept the EMC challenge before us. There is no doubt that assuring medical device electromagnetic compatibility will require the continued efforts of voluntary standards organizations, manufacturers, wireless service providers, test labs, regulators and health care providers. The cellular industry has displayed its commitment by focusing energy and resources on EMC concerns. We look forward to working with all sectors in the technological revolution to ensure that all the benefits that can possibly be derived from wireless products are safely delivered. Thank you for the opportunity to present our position to you today.

Mrs. THURMAN [presiding]. Thank you. I apologize for being late. However, with that, I am going to ask Mr. Thomas to go ahead with any questions that he might have.

Mr. THOMAS. Thank you. You mentioned a letter that I had nothing to do with. It states "At least five deaths have been tied to EMI problem, according to FDA records. The problem isn't limited to cellular phones. Some EMI comes from medical devices themselves that use wireless transmission to report patient data. Other devices such as pagers, walkie-talkies, and cordless phones also have been reported to cause problems with medical devices, according to Jeffrey Silberberg, senior engineer for the FDA Office of Science and Technology of the Center for Devices and Radiological Health. That's apparently where the five deaths are."

How do you react to that?

Mr. STUPKA. First, any loss of life or injury to patient is tragic. Again, the whole issue of compatibility relates to the intensity of the field and the shielding or the susceptibility of the device, if you will. I think, as we move toward a wireless society, as we start making ourselves more efficient and our care more intense through the use of wireless technology, that's going to be important that the industries work together to make sure that potential interaction is identified, understood, eliminated where possible and mitigated where it can't be eliminated.

Mr. THOMAS. But you don't quarrel with the fact there were five deaths associated with this phenomenon?

Mr. STUPKA. No.

Mr. THOMAS. Both of you, I think, mentioned this conference in Dallas. What were the fundings? What was the result of that? What will happen as a result of the conference?

Mr. STUPKA. The conference in Dallas was a first step. It was—when this issue of compatibility between medical devices and wireless devices came up, the wireless industry, through four of its principal members, commissioned the University of Oklahoma to do an environmental study, if you will, and frame the issue. Two or three things came up very clearly. One of them is the wireless industry. By its nature, our products are designed to emit.

We have very good standards. We operate under standards so our emissions are known. We have a large cohesive industry association because we have to interoperate all of our systems. So we were in a good position to commission someone to do the study. The results of the study basically were that it would be important for a focusing point to be developed to take the wireless industry and the medical industry and get them working in concert.

Unlike the cellular industry, which is limited by franchises and a number of players and licenses and standards today, the medical industry, to the best of our calculation, has about 13,000 manufacturers, and the largest trade association, which is HIMA, accounts for less than 1,000 of them.

There is—the people who manufacture MRI equipment, the people that manufacture blood pressure monitoring equipment don't have a lot in common. So someone needed to step up and take the lead in forming some kind of a center to get forms started, to provide testing facilities, to provide ways of focusing on compatibility issues. Again, the University of Oklahoma has formed that center now, and both CTIA and HIMA are very active in making sure that it is put to good use.

Mr. THOMAS. Would you like to comment?

Mr. SWANSON. Yes, I would—I would endorse his comments. I think the medical device industry is much more diverse and some devices are not affected at all by electromagnetic interference and some are. And I think speaking on behalf of the pacemaker industry, we have always had a strong sensitivity to that and as I mentioned, we have already undertaken with the Cellular Phone Industry Association to develop a protocol, to conduct the tests at the University of Oklahoma which we think will be very beneficial. And I expect others will follow in that direction, as well.

Mr. THOMAS. With such a diverse group of manufacturers, relatively few of them in one group, how can you have some kind of common self-discipline in the industry?

Mr. SWANSON. Well, I think there are two parts to that. One, I think that the Health Industry Manufacturers Association, although it does not represent all of the individual companies, represents a large spectrum of the affected devices in one way or another. And I think they have a strong role to play. FDA also, in its oversight function over medical devices, I think, will be playing a key role in ensuring that new devices that are brought to market do show the necessary test immunity.

Mr. THOMAS. Do these devices generally fall within the jurisdiction of the FDA?

Mr. SWANSON. The medical devices would all fall under the jurisdiction of FDA.

Mr. THOMAS. You already have that.

Mr. SWANSON. Correct. I think it is very clear that the sensitivity to—on the part of FDA to electromagnetic compatibility associated with cellular phones and other wireless communications devices—is going to be increased.

Mr. THOMAS. A little on the fringe, how long does it take, typically, to get a clearance from FDA for a device?

Mr. SWANSON. Well, today, it varies anywhere from approximately 9 months for a 510(k) or substantial equivalents device to approximately 2 years for those going through the full premarket approval process.

Mr. THOMAS. Thank you for being here. Appreciate it.

Mrs. THURMAN. Mr. Horn.

Mr. HORN. Thank you very much, Madam Chairwoman.

Mr. Swanson, let me ask you, is OSHA involved in any of these situations in terms of hospitals and medical equipment that's related there and possible hazards to employees?

Mr. SWANSON. I don't know that I can respond to the question of OSHA's participation with hospitals. I really don't know what their role is.

Mr. HORN. Well, I was curious, because one possibility to reduce the interference with these signals, whatever source, would be, I assume, to move heart monitors in hospitals away from where there are busy corridors and sort of have some protection that way, if you are in an emergency room or operating room situation.

And I'm just wondering if there has been any thought given to the rearrangement of various machines in relation to people, in relation to where people are walking by, be it with cellular phones or any other electronic equipment.

Mr. SWANSON. I think that's an excellent point, and I think that is something which today is clearly an obligation of the hospitals themselves to understand the EMI environment within their hospital, know what the sources of emissions are and what the effects would be on their devices.

Mr. HORN. I would think the Health Industry Manufacturers Association could render a real service if they brought the right people together to get them thinking in those terms, if indeed that's a problem. First, it has to be shown one way or another to what degree the power is a real problem. But if it is, it could be mitigated by some creative rearrangements here and awareness of professional staffs and others in hospitals or any other work situation.

Mr. SWANSON. I should comment that we in the pacemaker industry have had inquiries from hospital, biomedical engineers and often from patients themselves regarding potential problems and we do our best to try to address those issues.

Mr. HORN. That's a response to a question, but does your industry spend any time, say, alerting doctors and hospitals to the potential danger to the exposure of some of these devices to ordinary electromagnetic impulses, such as lightning, fluorescent lights, TV, other common sources?

Mr. SWANSON. We certainly do. Again, speaking on behalf of the pacemaker industry which I know the most about, we do warn about the effects of certain types of radiation that we know about. Obviously it is not possible to know what all the potential sources might be.

Mr. HORN. Who warns the patients when they are utilizing these devices at home? Is it the doctor? Is it the industry making the equipment? For instance, when a consumer goes in and gets a prescription from a doctor, in very small print that no one can possibly read, sometimes the label states the side-effects when bought at the pharmacy.

Are the side-effects noted and the dangers noted in some of this equipment?

Mr. SWANSON. Most of that information would be transmitted by the physician. Again, in the pacemaker industry, we also provide booklets for the patients themselves, which would give them information on the operation of their device, which would include things like the potential for EMI.

Mr. HORN. And somebody's looked at it so it is written for the consumer to understand, not simply the engineers to communicate with each other?

Mr. SWANSON. I would hope so.

Mr. HORN. I have a real thing about putting together——

Mr. SWANSON. I understand.

Mr. HORN. Children's toys or whatever, they have got the wrong people writing the manuals often. So thank you very much. Enjoyed the testimony of both of you gentlemen.

Mrs. THURMAN. Mr. Stupka, maybe to followup on Mr. Horn's question, when you sell these phones or as you are going through this, do you in fact do anything to your customers or let them know about potential problems?

Mr. STUPKA. There is a—there is a labeling process and as an industry, we are moving forward as the industry advances to constantly work and advance the labeling process. We are in the process right now of coming up with a new standardized labeling in all devices that talks about their functioning in various environments, health effects, issues and concerns, things of this nature. So again, we try to do it.

Now, one thing we are all going to have to come to grips with is that the environment is becoming mobile. The health care environment is becoming mobile. So while rearranging the equipment in a room may mitigate the problem within that room, one of the goals of the health care system in this country is to get the patient out of the acute-care facility and to monitor them through wireless means. So it is really key for us as industries to—to properly merge these two vital, useful products.

And again, we—I can speak for the wireless industry, we are very excited with what is being done at the University of Oklahoma. We're very excited about the response from HIMA and its members.

Mrs. THURMAN. Evidently this question was asked, I think, to the first panel, as well, about a recent issue of Microwave News detailing concerns about the experience of the new digital cellular telephones in Europe and these articles have claimed that digital cellular telephones interfere with pacemakers.

Are you aware of these articles and this situation, and can you give us any indication of what the cellular industry has done in response to this?

Mr. STUPKA. I think this would be a great way to explain how we are working together. We are aware of the studies. And basically what the studies say is that, in normal operation, there seems to be no problem. And if the device is put at full power extremely close to the pacemaker, that it could cause the pacemaker to have an extra beat or different beat, but upon being removed, the pacemakers return, is my understanding of the study.

Since that was based on the European studies and it raises a concern, the prudent thing to do would be for the health industry, the wireless industry and the FDA to work together to develop a test protocol and to test all the American standards. That is exactly what is under way.

Mr. SWANSON. Yes. Pacemakers are typically implanted in the upper chest right near the collarbone and if the telephone is in the pocket, the shirt pocket or jacket pocket, there is a potential for those phones to affect operation. But when you put it up to your ear, the distance is generally sufficient that it is not going to be a problem, at least that's been our experience with the analogue phones.

And one of the things that we are very interested in doing in a timely basis is working with the Cellular Phone Trade Association to test that at the University of Oklahoma, look at the effect of these new digital phones and make sure that we understand them and can advise our users properly and take any appropriate design actions we need.

Mrs. THURMAN. Is this beyond other medical equipment, as well? We're not just talking about pacemakers. I mean, is that what you're saying here as the digital phone comes in? I mean, are you testing them now, before they become in everybody's pocket and on all medical equipment or in other areas or——

Mr. STUPKA. What we need to do as the industry is basically work up the protocols for testing and to provide a place where people can economically take devices in and test for compatibility. It would not be—it takes a multi-million dollar laboratory to test for compatibility, to have the equipment that generates all the scenarios from the emitting device to have the equipment that records the output. It wouldn't be reasonable to expect 13,000 manufacturers to each have one of these facilities. So we are going to provide a place in the protocols so that in the future, there would be no reason to not have reasonable compatibility.

Mrs. THURMAN. And this would also work with other wireless devices, as well?

Mr. STUPKA. Absolutely. CTIA represents the entire wireless industry. So, for example, when we do the test with the pacemaker industry on pacemakers, we won't be testing analogue cellular. We will be testing analogue, digital, ESM. Even though it is a European standard, it may come to this country one day. We'll be testing enhanced mobile radio. We'll be testing every major protocol, if you will, that's used by us to transmit messages.

Mr. SWANSON. Let me just amplify in a couple of areas. I agree that the testing is going to be very valuable. One of the things we have to recognize is that we can and I expect we will improve the EMI resistance of new devices, but we are going to be living with devices that are already out there, whether they be in hospitals or whether they be with patients, and we are going to have to have solutions for both.

Obviously, one of the solutions for patients or those units that are already in place is to increase the distance. Because as you increase the distance, as they showed in their video, the susceptibility goes down very quickly. And so I think we have two parts to that solution.

Mrs. THURMAN. I think one of the things that we always worry about, too, in government is taking the information from the private industry and working and distributing that information with our Federal agencies and, in this case, of course, FDA. What kinds of efforts are we taking now for the industry and undertaken to date with FDA to put these partnerships together and what might we expect for future?

Mr. SWANSON. Well, I think FDA did participate in the conference down in Dallas last week. We've already, both the cellular phone and the pacemaker industry, had one meeting with FDA. We expect them to be involved in the protocols that are developed and in the testing that is conducted. They will obviously be reviewing the results on any new devices that we provide, so I expect them to be an active partner in this process.

Mrs. THURMAN. So they'll be getting these devices prior to them actually reaching the market or——

Mr. SWANSON. For new devices, absolutely. They have to be approved by FDA before we can distribute them.

Mrs. THURMAN. Is that also true with the cellular?

Mr. STUPKA. No. The FCC regulates cellular. But, again, we are under standards. So our emissions are known when we are licensed.

Mrs. THURMAN. The cellular telephone industry is planning to sponsor research on potential human health risk associated with electromagnetic energy from cellular phones.

What is the status of this research?

Mr. STUPKA. The status of the research is, again, any good scientific program has a bit of rigor to it. We have a separate scientific advisory group. This group basically did a—took the time to review all the available research that has been done over the last 20 years. From it, they came up with a plan that was what research would be necessary to give further comfort to others that there are no health effects associated with wireless. That final report has been completed. It has been peer reviewed. It has been reviewed by the Harvard Center For Public Health Risk Assessment, and now the research is coming up.

Mrs. THURMAN. Mr. Swanson, before they are offered for public sale, what testing do medical devices receive regarding electromagnetic interference and does any testing specifically address nearby cellular phones or other electromagnetic sources?

Mr. SWANSON. I think the amount of testing and the type of testing that each medical device is subjected to before it is put on the market varies with the particular medical device. Again, for those that have known susceptibility to electromagnetic interference, such as pacemakers or apnea monitors, there is a significant amount of electromagnetic test—compatibility testing that each company conducts, and those data are submitted to FDA for their review as a part of the premarket approval process.

Mrs. THURMAN. Mr. Horn, do you have some?

Mr. HORN. No, thank you, Madam Chairwoman.

Mrs. THURMAN. We have a few other questions here, but I think what we would like to do is maybe be able to submit them to you, both of you, and answer in a written form.

[The information referred to follows:]

Eastern Maine Healthcare

489 State St. • Bangor, ME 04401 • 207-945-7045 • Fax: 207-945-8995
Internet: gregory@saturn.caps.maine.edu

October 4, 1994

Congressman Gary Condit
Government Operations Sub-Committee
Information, Justice, Transportation and Agriculture
Via FAX to 202-225-2445

Statement for Public Hearing, Oct 5, 1994.

Dear Congressman Condit.

Thank you for your interest in our problem with electromagnetic compatibility. I am Director of Information Technology Projects for Eastern Maine Medical Center, a 400 bed tertiary care facility in Bangor Maine. As such, I am involved in the introduction of new technologies.

Recent requests from our clinical staff for RF devices such as cell phones and wireless computer networks prompted me to question the patient safety aspects of RF technology, when used in close proximity to sensitive clinical devices. Our engineering staff has discovered that using a hand held transmitter within several feet of a ground fault interrupt device can cause the GFI to turn off, stopping electrical power to the controlled circuit.

I posted a note on the Internet requesting information from others who had similar experiences. Within several days I received many anecdotal reports of the erratic operation of devices like respirators, wheel chairs and fire alarms. Although the direct cause is difficult to determine, most reports provide a clear indication that the mix of transmitters and clinical devices did indeed put patients at a real and present risk.

Our Risk Management Committee will soon ban all radio transmitters for much of our facility. Further, I have recommended the suspension of a pilot project to use wireless computer networks to facilitate the prompt reporting and evaluation of clinical data.

RF technologies present an attractive and effective advancement in information technology, much needed in medical facilities. The advanced, computer controlled clinical equipment is likewise providing a much needed assist to effective health care. It is imperative that performance standards for electromagnetic compatibility be developed as rapidly as possible.

Sincerely yours,
Ron Gregory
Director, Information Technology Projects
Eastern Maine Healthcare.

Mrs. THURMAN. We appreciate you being here, your testimony. This meeting is adjourned.

[Whereupon, at 10:20 a.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

APPENDIX

Gary A. Condit, California, Chairman
Major Owens, New York
Karen Thurman, Florida
Lynn Woolsey, California
Bart Stupak, Michigan

Craig Thomas, Wyoming
Ranking Minority Member
Ileana Ros-Lehtinen, Florida
Stephen Horn, California

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Information, Justice, Transportation, and Agriculture
Subcommittee
of the
Committee on Government Operations
B-349-C Rayburn House Office Building
Washington, DC 20515

VOICE (202) 225-3741
FAX (202) 225-2445

October 26, 1994

Dr. Thomas Stanley
Director, Office of Plans and Policy
Federal Communications Commission
1919 M Street, N.W.
Washington, DC 20554

Dear Dr. Stanley:

In follow-up to the October 5, 1994 hearing on electromagnetic interference, enclosed pleased find a series of questions on matters raised during testimony and the subsequent Subcommittee questioning process. Responses to these questions will be made part of the formal hearing record. I would appreciate if you would respond by November 15, 1994.

Of course, I very much appreciate your cooperation and assistance in the October 5, 1994 hearing. It is clear the cellular and wireless industry, the medical device manufacturing industry, and other effected medical interests, working with the FDA and the FCC, have a unique opportunity to promptly address and resolve the EMI issue. The Subcommittee intends to continue to monitor developments in this area, and the hearing record will serve as a benchmark document for future work in this area.

Again, I appreciate your cooperation.

Sincerely,

Gary A. Condit
Chairman

Questions for Mr. Stanley, representing the FCC:

1) Has the FCC tested GSM-standard digital cellular telephones, such as those currently used in the European community, for electromagnetic interference? If not, does the Commission have plans to do so?

2) Describe the level and scope of FCC staff communications and cooperation with the FDA on EMI-related matters.

3) Describe the level and scope of FCC staff communications and cooperation with the cellular manufacturing industry on EMI-related matters.

4) The testimony of Mr. Chuck Swanson, representing the Health Industry Manufacturers Association, outlined five policy recommendations. See attachment #1. Please comment on or provide a reaction to his suggestions.

5) Representatives of one leading cellular manufacturer have predicted that Americans will use 100 million cellular telephones by the year 2000. Please describe the planned FCC activities to proactively address potential EMI-related issues involving sensitive medical devices.

6) The FDA document, "EMI Protection Distance," August 15, 1994, outlines the minimum distance that should be maintained between transmitters and medical devices (in meters). Please comment further on how this document could be used to establish effective EMC standards or guidelines.

7) The FDA document lists various immunity levels of medical devices (e.g. 1 V/m, 3 V/m, etc.). Please provide the immunity levels for the following medical devices: 1) pacemakers, 2) hearing aids, 3) electric wheelchairs and motorized scooters, 4) apnea or SIDS monitors, 5) blood gas pumps, and 6) heart monitors.

Federal Communications Commission
Washington, D.C. 20554

December 2, 1994

The Honorable Gary A. Condit
Chairman, Subcommittee on Information,
Justice, Transportation, & Agriculture
Committee on Government Operations
United States House of Representatives
B-349-C Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Condit:

This is in reference to your letter of October 26, 1994, requesting responses to follow-up questions related to matters raised during testimony at the recent hearing on electromagnetic interference to medical devices. The answers are enclosed.

I hope that the responses will be helpful to you and your Subcommittee. If you have additional questions, please do not hesitate to contact me.

Sincerely,

Thomas P. Stanley

Thomas P. Stanley
Chief Engineer
Office of Plans & Policy

Enclosures

QUESTIONS & ANSWERS FOR EMI HEARING

Question 1. Has the FCC tested GSM-standard digital cellular telephones, such as those currently used in the European community, for electromagnetic interference? If not, does the Commission have plans to do so?

Answer 1: The Commission has not tested GSM-standard digital cellular telephones because these telephones are not being used in the U.S. We have no plans to test cellular telephones, such as GSM-standard digital cellular telephones, unless they would be used in the U.S. FCC rules require that U.S. cellular telephones comply with technical standards that are intended to reduce the probability for harmful interference being caused to other radio users. These standards address the ability of cellular telephones to operate within their prescribed bandwidths, the amount of radio frequency energy emitted within the authorized cellular bands, and the amount of radio frequency energy emitted outside of the spectrum allocated for cellular operation. We require that each model of cellular telephone be tested by a qualified laboratory to show compliance with these standards. We then review the results of these tests before we authorize the marketing of that model. When warranted, we can also perform our own equipment testing to ensure that cellular telephones comply with the technical standards.

These tests are intended to reduce harmful interference being caused to other radio users. These tests, however, do not address the ability of medical or other electronic devices to function in the presence of communications signals. As mentioned in previous testimony, the more comprehensive, long-term and practical solution to the electromagnetic compatibility problem is to make the medical devices more immune to interfering transmissions.

Question 2. Describe the level and scope of FCC staff communications and cooperation with the FDA on EMI-related matters.

Answer 2. In the past FCC and FDA staff have worked together to investigate specific EMI cases, when involvement of an FCC-regulated transmitter has been alleged. Commission staff have met with FDA staff on other occasions to discuss more generally potential EMI problems relating to medical devices. In August of this year, FCC staff met with FDA personnel from the FDA's Center for Devices and Radiological Health (CDRH) at CDRH headquarters in Rockville, Maryland, to determine ways in which the two agencies could cooperate in solving potential EMI problems associated with transmitters regulated by the FCC. In October of this year, senior Commission staff and management met with Dr. Bruce Burlington, Director of the CDRH, and other CDRH personnel at FCC headquarters to further pursue this matter. It has been agreed that FCC and CDRH staff will continue inter-agency consultations and exchanges of information on the most effective approaches to electromagnetic compatibility problems.

Question 3. Describe the level and scope of FCC staff communications and cooperation with the cellular manufacturing industry on EMI-related matters.

Answer 3. The Commission maintains continuing communications with industry officials relating to this issue. On several occasions cellular industry officials have met with Commission management and staff to discuss their concerns. Also, FCC officials have participated in various industry forums where this topic has been addressed. For example, I recently attended and participated in a conference held in Dallas, Texas, and sponsored by the cellular industry and medical device manufacturers, where this topic was extensively discussed.

Question 4. The testimony of Mr. Chuck Swanson, representing the Health Industry Manufacturers Association, outlined five policy recommendations. See attachment #1. Please comment on or provide a reaction to his suggestions.

Answer 4. As discussed in my testimony before the Subcommittee, the Commission believes that designing medical devices to provide greater levels of immunity to EMI is the preferable solution to this problem. Therefore, of the five suggestions listed by Mr. Swanson, we would be inclined to emphasize his suggestion number 3. We also can see merit in suggestions 4 and 5 dealing with establishment of testing requirements and cooperation between the cellular industry and medical device manufacturers. However, at this time the Commission does not believe that banning or severely restricting the use of cellular telephones in medical environments as proposed in suggestions 1 and 2 is a viable long-term solution.

Question 5. Representatives of one leading cellular manufacturer have predicted that Americans will use 100 million cellular telephones by the year 2000. Please describe the planned FCC activities to proactively address potential EMI-related issues involving sensitive medical devices.

Answer 5. The most effective measures that the FCC can take to address potential EMI-problems with electronic devices, including medical devices, would be to inform and educate the public and the appropriate communities, including the manufacturers, on the continually evolving electromagnetic environment of new service and technologies. As a general matter, the FCC does not have the authority, expertise or resources to test and evaluate electronic devices, including medical devices, for potential EMI problems. We believe that the key to proactively addressing potential EMI problems should be based on educational activities and coordination between the federal agencies that have responsibilities in this area. It is not possible to foresee all potential EMI-related problems involving medical devices due to the great variety of electromagnetic environments in which a device may be operated. Therefore, we continue to emphasize the need for increased electromagnetic immunity levels for medical devices as a preventative measure. Responsibility for such testing and evaluation resides with the FDA's CDRH. We intend to cooperate with the FDA in alerting it to new regulated services and technologies that may generate new electromagnetic signals with changed potential for interference.

Question 6. The FDA document, "EMI Protection Distance," August 15, 1994, outlines the minimum distance that should be maintained between transmitters and medical devices (in meters). Please comment further on how this document could be used to establish effective EMC standards or guidelines. (See pp. 19 & 26 of the transcript.)

Answer 6. The FDA draft document, entitled "EMI Protection Distance," was given to Federal Communications Commission (FCC) staff at an inter-agency staff meeting held at the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) on August 15, 1994. The purpose of the meeting was to discuss the issue of potential electromagnetic interference to medical devices, and how the FCC and the CDRH might work together to try and resolve problems that might arise with respect to this issue.

The document contains a table showing how levels of increasing immunity to (protection from) EMI for medical devices could be correlated with distances from various transmitters of radiofrequency (RF) energy. In other words, if one were to maintain the stated distance from a given transmitter and if the medical device in question had the stated level of immunity, then there should not be an EMI problem, at least theoretically.

This table was developed using a mathematical relation that indicates minimum separation distance is proportional to the square root of the power and the inverse of the immunity level. This is explained on the reverse side of the document. The table contains an explanation of the limitations of the mathematical equation used and states that the recommended protection distances are approximate. The authors of the table intend to revise the values listed based on updated information. Actual protection distance is affected by antenna efficiency and radiation pattern; multipath reflections; and absorption by objects such as buildings and people. Reflections could increase the protection distances while absorption could decrease them. These levels were calculated using the maximum power allowed by the FCC for each respective type of transmitter and only single emitters were used to calculate each distance. Worst-case assumptions were made with respect to the electromagnetic susceptibility of the medical device.

As we understand it, this document was only meant to be a point of discussion among FDA staff. The table was not intended to be a precursor to a regulatory action by the FDA. It should be viewed as a draft document to be used for research and discussion purposes only. The table represents a scientific approach to understanding the problem but should not be read as giving a definitive indication of whether EMI might occur to a specific medical device in a given situation. We caution against using the document to support actions that would limit use of telecommunications devices in certain environments or would lead to conclusions concerning the safe operation of medical devices in places where electromagnetic emissions may be above a certain level.

Question 7. **The FDA document lists various immunity levels of medical devices (e.g. 1 V/m, 3 V/m, etc.). Please provide the immunity levels for the following medical devices: 1) pacemakers, 2) hearing aids, 3) electric wheelchairs and motorized scooters, 4) apnea or SIDS monitors, 5) blood gas pumps, and 6) heart monitors.**

Answer 7. The FDA is the expert agency with regulatory authority for establishing immunity levels for medical devices. The FCC does not have jurisdiction to establish such immunity levels. As we understand it, the FDA has been active in this area with respect to electronic pacemakers (heart monitors), apnea monitors and electronic wheelchairs. With respect to electronic pacemakers, although the FDA does not have mandatory EMC standards, applicants for FDA approval are required to submit information on immunity levels. One commonly used standard is 200 volts-per-meter (V/m) at a test frequency of 450 megahertz (MHz). In the case of apnea monitors we understand that the FDA is now asking applicants to supply information on immunity and that the target immunity level is 3 V/m. With respect to electronic wheelchairs the FDA has recently performed extensive testing on these devices, and, according to FDA officials, a specific proposal has been developed for a target immunity level of 20 V/m. Furthermore, in May of this year the FDA sent a letter to electronic wheelchair manufacturers recommending the 20 V/m level as well as labeling of wheelchairs with respect to EMI potential.

JOHN CONYERS, JR., MICHIGAN,
CHAIRMAN

CARDISS COLLINS, ILLINOIS
HENRY A. WAXMAN, CALIFORNIA
MIKE SYNAR, OKLAHOMA
STEPHEN L. NEAL, NORTH CAROLINA
TOM LANTOS, CALIFORNIA
MAJOR R. OWENS, NEW YORK
EDOLPHUS TOWNS, NEW YORK
JOHN M. SPRATT, JR., SOUTH CAROLINA
GARY A. CONDIT, CALIFORNIA
COLLIN C. PETERSON, MINNESOTA
KAREN L. THURMAN, FLORIDA
BOBBY L. RUSH, ILLINOIS
CAROLYN B. MALONEY, NEW YORK
THOMAS M. BARRETT, WISCONSIN
DONALD M. PAYNE, NEW JERSEY
FLOYD H. FLAKE, NEW YORK
JAMES A. HAYES, LOUISIANA
CRAIG A. WASHINGTON, TEXAS
BARBARA-ROSE COLLINS, MICHIGAN
CORRINE BROWN, FLORIDA
MARJORIE MARGOLIES-MEZVINSKY, PENNSYLVANIA
LYNN C. WOOLSEY, CALIFORNIA
GENE GREEN, TEXAS
BART STUPAK, MICHIGAN

ONE HUNDRED THIRD CONGRESS

Congreſs of the United States

House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

WILLIAM F. CLINGER, JR., PENNSYLVANIA
RANKING MINORITY MEMBER
AL McCANDLESS, CALIFORNIA
J. DENNIS HASTERT, ILLINOIS
JON L. KYL, ARIZONA
CHRISTOPHER SHAYS, CONNECTICUT
STEVEN SCHIFF, NEW MEXICO
C. CHRISTOPHER COX, CALIFORNIA
CRAIG THOMAS, WYOMING
ILEANA ROS-LEHTINEN, FLORIDA
DICK ZIMMER, NEW JERSEY
WILLIAM H. ZELIFF, JR., NEW HAMPSHIRE
JOHN M. McHUGH, NEW YORK
STEPHEN HORN, CALIFORNIA
DEBORAH PRYCE, OHIO
JOHN L. MICA, FLORIDA
ROB PORTMAN, OHIO
FRANK D. LUCAS, OKLAHOMA

BERNARD SANDERS, VERMONT
INDEPENDENT

MAJORITY—(202) 225-5051
MINORITY—(202) 225-5074

November 1, 1994

Mr. Reed E. Hundt
Chairman
Federal Communications Commission
1919 M Street, NW
Washington, D.C. 20554

Dear Mr. Hundt:

Pursuant to Rules X and XI of the House of Representatives, the Committee on Government Operations' Subcommittee on Information, Justice, Transportation and Agriculture conducted an oversight hearing on October 5, 1994, to review the Federal Communications Commission's (FCC) regulation of wireless technology and its effect on electronic medical equipment. During the hearing, Dr. Thomas Stanley, Chief Engineer of the Office Plans and Policy Division for the FCC, testified of instances where the agency has exempted particular devices from regulations for which there have been no electronic magnetic interference (EMI) complaints. I request that the FCC provide specific examples of such deregulation. The information will be submitted for the record.

In furtherance of this request, the subcommittee would appreciate receiving responses to the following questions by C.O.B., Friday, November 18, 1994:

1) Please describe the jurisdiction that the FCC has under Part 15 of the Code of Federal Regulations;

2) Does Part 15 or other law give the FCC the authority to regulate immunity standards for electronic equipment used in the home;

3) Has the FCC acted under this authority? Please explain why or why not;

4) Has the FCC investigated the issue of interactivity between radio equipment and medical devices;

5) Is the FCC taking action to lower the permissible power levels of handheld transmitters such as walkie-talkies; and

6) Will this help achieve electromagnetic compatibility?

Thank you in advance for your cooperation. Please contact Diane Major of the minority subcommittee staff at (202) 225-2738 if you have any questions.

Best regards,

Craig Thomas
Ranking Minority Member
Subcommittee on Information, Justice
Transportation and Agriculture

cc: Dr. Thomas P. Stanley, Chief Engineer
Office Plans and Policy

Judith L. Harris, Director
Legislative Affairs

Federal Communications Commission
Washington, D.C. 20554

December 2, 1994

The Honorable Craig Thomas
Ranking Minority Member
Subcommittee on Information, Justice,
Transportation & Agriculture
Committee on Government Operations
United States House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Congressman Thomas:

This letter responds to your letter to Chairman Hundt of November 1, 1994, requesting responses to follow-up questions for the recent hearing on electromagnetic interference to medical devices. The answers are enclosed.

I hope that the responses will be helpful to you and your Subcommittee. If you have additional questions, please do not hesitate to contact me.

Sincerely,

Thomas P Stanley

Thomas P. Stanley
Chief Engineer
Office of Plans & Policy

Enclosures

B. Industrial, Scientific, and Medical Equipment

Industrial, scientific and medical (ISM) devices are products that use radio frequency energy to perform work or produce physical changes, excluding applications for telecommunications. These products are normally subject to regulation under Part 18 of our rules. The following ISM devices are exempt from these standards, pursuant to 47 CFR Section 18.121:

- Non-consumer ultrasonic equipment used for medical diagnostic and monitoring applications; and,

- Magnetic resonance equipment used for medical diagnostic and monitoring applications.

NOTE: All of the products described above operate under the condition that they not cause harmful interference to other users of the radio spectrum.

* * * * * * * *

The following responses are provided to the six questions posed in your November 1, 1994, letter.

Question 1: **Please describe the jurisdiction that the FCC has under Part 15 of the Code of Federal Regulations.**

Answer 1. The FCC's jurisdiction for all of its rule parts is contained in the Communications Act of 1934, as amended, also known as Title 47 of the U.S. Code. Among other things, this Act authorizes the Commission to license radio stations, assign frequencies, establish regulations necessary to prevent interference between stations, and regulate the interference potential of devices that are capable of emitting radio frequency energy. Part 15 of the Code of Federal Regulations contains the standards that the FCC has adopted for limiting the potential of harmful radio interference from various electronic devices, including low-power transmitters that can be operated without a license.

Question 2: **Does Part 15 or other law give the FCC the authority to regulate immunity standards for electronic equipment used in the home?**

Answer 2. The authority that enables us to establish immunity standards for electronic equipment used in the home is contained in 47 U.S.C. Section 302(a). That section states that "[t]he Commission may, consistent with the public interest, convenience, and necessity, make reasonable regulations ... establishing minimum performance standards for home electronic equipment and systems to reduce their susceptibility to interference from radio frequency energy." This authority was established under Public Law 97-259, 96 Stat. 107, 1091-92, September 13, 1982.

You requested at page 21 of the transcript that the Commission provide examples of particular electronic devices that have been exempted from regulations because there have been no electromagnetic interference (EMI) complaints. The Commission has exempted several types of devices from technical and equipment authorization requirements. These devices, in general, operate with such low power or in such environments that interference is unlikely to occur or can be controlled by the user. The list follows:

PRODUCTS EXEMPT FROM FCC EMISSION STANDARDS

A. Digital Devices

Digital devices, such as computer circuitry, normally are subject to the technical standards and equipment authorization requirements contained in Part 15 of our rules. The following digital devices are exempt from these standards, pursuant to 47 CFR Section 15.103:

- Digital devices used exclusively in any transportation vehicle including motor vehicles and aircraft;

- Digital devices used exclusively as an electronic control or power system utilized by a public utility or in an industrial plant;

- Digital devices used exclusively as industrial, commercial or medical test equipment;

- Digital devices used exclusively in an appliance, e.g., a microwave oven, dishwasher, clothes dryer, or air conditioner;

- Specialized medical digital devices, i.e., devices used at the direction of or under the supervision of a licensed health care practitioner;

- Digital devices that have a power consumption not exceeding 6 nanowatts;

- Joystick controllers or similar devices, such as a mouse, used with digital devices and containing only non-digital circuitry or a simple circuit to convert the signal to the format required, e.g., an integrated circuit for analog to digital conversion; and,

- Digital devices in which both the highest frequency generated and the highest frequency used are less than 1.705 megahertz and which do not operate from the AC power lines or contain provisions for operation while connected to the AC power lines.

Question 3: **Has the FCC acted under this authority? Please explain why or why not.**

Answer 3. The FCC has not adopted any regulations regarding the immunity of home electronic equipment to radio frequency interference. This type of interference affects only a small percentage of the total number of users of home electronic equipment. Accordingly, the Commission relies upon industry to develop appropriate solutions to immunity problems. To date, immunity standards have been voluntarily implemented for television broadcast receivers. This industry-developed solution has proved to be viable and economically feasible, and has significantly reduced interference in television receivers. Industry is currently developing immunity standards for telephone equipment as well.

Question 4: **Has the FCC investigated the issue of interactivity between radio equipment and medical devices?**

Answer 4. In the past the FCC has been involved in such investigations only to a limited extent. For example, in the late 1970s, FCC staff participated in an investigation of a case of interference to an implanted cardiac pacemaker allegedly caused by a Citizen's Band radio transmitter. Since then, there have been a few similar cases of alleged electromagnetic interference (EMI) to pacemakers due to either CB or amateur transmissions. In these instances, FCC staff participated to a limited extent in the investigation, primarily for the purpose of measuring the electromagnetic fields created by the transmitter in question. There was also at least one case of EMI to a baby monitor that was allegedly caused by an amateur transmitter. However, in all of these cases, the problems were not shown to be due to radio transmissions but rather to problems with the medical equipment. Most of the cases where EMI to medical devices has been suspected have been investigated by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). In a few of these investigations the FCC has worked with the FDA in assisting with field measurements or by providing the FDA with other relevant information from FCC databases.

Questions 5 and 6: **Is the FCC taking action to lower the permissible power levels of handheld transmitters such as walkie-talkies? Will this help achieve electromagnetic compatibility?**

Answers 5 and 6. We have not proposed to lower the permitted power levels of handheld transmitters. Reducing the permitted power levels of handheld transmitters could help, but would not ensure, electromagnetic compatibility. As stated in my previous testimony, the more comprehensive, long-term and practical solution to the electromagnetic compatibility problem in most cases is to make medical devices more immune to undesired transmissions. Medical devices operate in the presence of many different sources of electromagnetic signals, not just handheld transmitters. Such signals also are generated by nearby receivers, computers, broadcast stations, and land mobile stations, including transmitters used in ambulances and biomedical telemetry systems used in hospitals. Hospitals also use radio frequency equipment operated under Part 18 of our rules for heating, sterilization, cauterizing scalpels, diagnostic and monitoring equipment, etc. In several frequency bands Part 18 devices operate without a restriction on output levels and, as such, may be more likely sources of interference than handheld transmitters. Restricting the proximity of certain transmitters to this equipment is not always feasible since there are a great many sources of radio frequency energy, especially in medical environments.

Gary A. Condit, California, Chairman
Major Owens, New York
Karen Thurman, Florida
Lynn Woolsey, California
Bart Stupak, Michigan

Craig Thomas, Wyoming
Ranking Minority Member
Ileana Ros-Lehtinen, Florida
Stephen Horn, California

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Information, Justice, Transportation, and Agriculture
Subcommittee
of the
Committee on Government Operations
B-349-C Rayburn House Office Building
Washington, DC 20515

VOICE (202) 225-3741
FAX (202) 225-2445

October 26, 1994

Mr. John Stupka
Chairman of the Board
Cellular Telecommunications Industry Association
1250 Connecticut Avenue, N.W.
Suite 200
Washington, DC 20036

Dear Mr. Stupka:

In follow-up to the October 5, 1994 hearing on electromagnetic interference, enclosed pleased find a series of questions on matters raised during testimony and the subsequent Subcommittee questioning process. Responses to these questions will be made part of the formal hearing record. I would appreciate if you would respond by November 15, 1994.

Of course, I very much appreciate your cooperation and assistance in the October 5, 1994 hearing. It is clear the cellular and wireless industry, the medical device manufacturing industry, and other effected medical interests, working with the FDA and the FCC, have a unique opportunity to promptly address and resolve the EMI issue. The Subcommittee intends to continue to monitor developments in this area, and the hearing record will serve as a benchmark document for future work in this area.

Again, I appreciate your cooperation.

Sincerely,

Gary A. Condit
Chairman

Questions for Mr. Stupka, representing CTIA:

1) New standards for electromagnetic interference (EMI) have been established for GSM-standard digital cellular telephones operating in the European community markets. Does the CTIA have a position, either formal or informal, on these new European EMI standards?

2) Describe the level and scope of FCC staff communications and cooperation with the cellular manufacturing industry on EMI-related matters.

3) The testimony of Mr. Chuck Swanson, representing the Health Industry Manufacturers Association (HIMA), outlined five policy recommendations. See attachment #1. Please comment on his suggestions.

4) Representatives of one leading cellular manufacturer have predicted that Americans will use 100 million cellular telephones by the year 2000. Please describe the planned CTIA activities to proactively address potential EMI-related issues affecting sensitive medical devices.

5) The FDA document, "EMI Protection Distance," August 15, 1994, outlines the minimum distance that should be maintained between transmitters and medical devices (in meters). Please comment further on how this document could be used to establish effective EMC standards or guidelines.

6) Representatives of the FDA have expressed concerns that new cellular or wireless products are not being tested for EMI before introduction to the domestic marketplace. Does the CTIA plan to require, or at least encourage, cellular or wireless manufacturers to provide the FDA with new products to be tested before they are sold to consumers in the U.S. market?

Building The
Wireless Future™

CTIA
Cellular
Telecommunications
Industry Association
1250 Connecticut
Avenue, N.W.
Suite 200
Washington, D.C. 20036
202-785-0081 Telephone
202-785-0721 Fax
202-736-3220 Direct Dial

Wallace J. Henderson
Vice President for
Congressional Affairs

December 1, 1994

The Honorable Gary Condit
Chairman
Subcommittee on Information, Justice Transportation and Agriculture
B-349C Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Condit:

Enclosed please find Mr. Stupka's responses to the follow-up questions submitted by the Subcommittee after the October 5, 1994 hearing.

CTIA appreciates the opportunity to respond to your concerns.

Sincerely,

Wallace Henderson

Wallace Henderson
Vice President of Congressional Affairs

Responses by John Stupka, to Follow-up Questions From The House Government Operations Subcommittee on Information Justice Technology and Agriculture

Question 1: New standards for electromagnetic interference (EMI) have been established for GSM-standard digital cellular telephones operating in the European community markets. Does the CTIA have a position, either formal or informal, on these new European EMI standards?

Response: This question involves two types of standards in Europe: emission standards and immunity standards. Emission standards apply to the technical operation of communications devices such as GSM wireless telephones. The United States also has emission standards for communications devices that are licensed here. Immunity standards apply to the manufacture of medical devices. The United States does not have similar standards for most medical devices. There has been no reason for CTIA to develop a position on the European standards.

As the revolution in digital signal processors (DSPs) and wireless technologies continues in the United States, it is CTIA's position that coordination and cooperation among the many affected industries will be needed to achieve electromagnetic compatibility.

Question 2: Describe the level and scope of FCC staff communications and cooperation with the cellular manufacturing industry on EMI-related matters.

Response: The FCC has a long history of addressing electromagnetic interference issues within the communications spectrum. FCC staff members work to ensure the rules are clear on the broad range of powers and frequencies on which modern communications devices operate. This allows manufacturers of medical and other electronic devices to determine the proper level of immunity for the electromagnetic environment in which the devices will operate.

Question 3: The testimony of Mr. Chuck Swanson, representing the Health Industry Manufacturers Association (HIMA), outlined five policy recommendations. See attachment #1. Please comment on his suggestions.

Response: I agree with Mr. Swanson's assessment that banning the use of wireless devices is an extreme and unwarranted measure. I also agree with Mr. Swanson's conclusion that option 5, cooperation between the wireless and medical device industries to ensure compatibility, is the most solid basis for a long-term solution. The wireless industry is committed to this course of action.

Question 4: Representatives of one leading cellular manufacturer have predicted that Americans will use 100 million cellular telephones by the year 2000. Please describe the planned CTIA activities to proactively address potential EMI-related issues affecting sensitive medical devices.

Response: The wireless industry recognizes that electromagnetic compatibility is the responsibility of all sectors involved in the digital revolution. The cellular industry has taken the lead and displayed its commitment by focusing energy and resources on electromagnetic compatibility concerns. The wireless industry has provided seed money needed to establish a Center for Wireless Electromagnetic Compatibility at the University of Oklahoma. These efforts will continue through educational forums, participation in standards setting bodies and support of programs such as the Center for Wireless Electromagnetic Compatibility, which provides medical device manufacturers with a test facility to evaluate the immunity of their devices in a wide range of electromagnetic environments.

Question 5: The FDA document, "EMI Protection Distance," August 15, 1994, outlines the minimum distance that should be maintained between transmitters and medical devices (in meters). Please comment further on how this document could be used to establish effective EMC standards or guidelines.

Response: It is my understanding that the FDA's August 15 chart is still in draft form. The various immunity levels set forth in the FDA draft are among the levels being addressed in the standards bodies. The distances are approximate worst-case calculations, and as FDA's accompanying explanation states, real world characteristics would cause the calculations to vary widely. Thus, it is difficult to determine if the chart would be useful in real-world situations.

Question 6: Representatives of the FDA have expressed concerns that new cellular or wireless products are not being tested for EMI before introduction to the domestic marketplace. Does the CTIA plan to require, or at least encourage, cellular or wireless manufacturers to provide the FDA with new products to be tested before they are sold to customers in the U.S. market?

Response: The FCC sets emission standards for communications devices, including cellular telephones. Communications devices are not regulated by the FDA and thus are not routinely submitted for testing although cellular manufacturers have worked voluntarily with the FDA when requested.

It is CTIA's position that the digital revolution will bring tremendous benefits to the health care community and that wireless and medical devices must be able to coexist to bring these benefits about. Electromagnetic compatibility will require the continued efforts of voluntary standards organizations, manufacturers, wireless service providers, test labs, health care providers and regulators. The wireless industry is committed to this goal and will continue to cooperate with regulators to advance electromagnetic compatibility of wireless and medical devices.

Gary A. Condit, California, Chairman
Major Owens, New York
Karen Thurman, Florida
Lynn Woolsey, California
Bart Stupak, Michigan

Craig Thomas, Wyoming
Ranking Minority Member
Ileana Ros-Lehtinen, Florida
Stephen Horn, California

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Information, Justice, Transportation, and Agriculture
Subcommittee
of the
Committee on Government Operations
B-349-C Rayburn House Office Building
Washington, DC 20515

VOICE (202) 225-3741
FAX (202) 225-2445

October 26, 1994

Mr. Charles H. Swanson
c/o Health Industry Manufacturers Association
1200 G Street, N.W.
Suite 400
Washington, DC 20005

Dear Mr. Swanson:

In follow-up to the October 5, 1994 hearing on electromagnetic interference, enclosed pleased find a series of questions on matters raised during testimony and the subsequent Subcommittee questioning process. Responses to these questions will be made part of the formal hearing record. I would appreciate if you would respond by November 15, 1994.

Of course, I very much appreciate your cooperation and assistance in the October 5, 1994 hearing. It is clear the cellular and wireless industry, the medical device manufacturing industry, and other effected medical interests, working with the FDA and the FCC, have a unique opportunity to promptly address and resolve the EMI issue. The Subcommittee intends to continue to monitor developments in this area, and the hearing record will serve as a benchmark document for future work in this area.

Again, I appreciate your cooperation.

Sincerely,

Gary A. Condit
Chairman

Questions for Mr. Swanson, representing HIMA:

1) Have Medtronic or other HIMA-member companies adjusted their product design of products intended for export to European community markets as a result of the new EMC standards recently implemented there? Have any HIMA-member companies been restricted in their ability to export due to these new EMC standards?

2) If the CTIA- and HIMA-sponsored EMC project at the University of Oklahoma results in new EMC standards for future medical devices, how will HIMA-member companies address the safety and efficacy concerns of products currently in the consumer marketplace? For example, if a pacemaker will require a change in shielding design, what steps will be taken for those individuals currently using implanted pacemakers?

3) Please list the medical device companies which have been contacted by the Food and Drug Administration (FDA) about possible electromagnetic interference problems. For example, FDA officials cite their work with various electric wheelchair and apnea monitor manufacturers on developing new immunity design standards.

4) Mr. Stanley of the FCC testified that he believed the FDA should take the lead federal role on EMI-related matters. Would you agree?

5) New standards for electromagnetic interference (EMI) have been established for GSM-standard digital cellular telephones operating in the European community markets. Does the CTIA have a position, either formal or informal, on these new European EMI standards?

6) Describe the level and scope of FCC staff communications and cooperation with the medical device manufacturing industry on EMI-related matters.

7) The FDA document, "EMI Protection Distance," August 15, 1994, outlines the minimum distance that should be maintained between transmitters and medical devices (in meters). Please comment further on how this document could be used to establish effective EMC standards or guidelines.

HIMA

December 1, 1994

Hon. Gary Condit, Chairman
Information, Justice, Transportation, and Agriculture Subcommittee
Committee on Government Operations
B-349-C Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I have enclosed per your request responses to the questions you posed for Dr. Charles Swanson, vice president, Medtronic, Inc. Dr. Swanson testified representing HIMA at the Subcommittee hearing on October 5, 1994. We have tried to be as responsive and informative as possible.

Should you have any further questions or desire additional information, please contact me at (202) 434-7230.

Sincerely,

Bernie Liebler
Director
Technology & Regulatory Affairs

Health Industry Manufacturers Association

1200 G STREET N W SUITE 400
WASHINGTON D C 20005 3814
(202) 783-8700
FAX (202) 783 8750

Follow-up Questions to October 5, 1994 Testimony of
Dr. Charles Swanson, vice president, Medtronic, Inc.
representing the
Health Industry Manufacturers Association (HIMA)

Question 1. Have Medtronic and other HIMA-member companies adjusted their product design of products intended for export to European community markets as a result of the new EMC standards recently implemented there? Have any HIMA-member companies been restricted in their ability to export due to these new EMC standards?

Answer 1. Although Medtronic has not had to modify its product designs to comply with European EMC standards, some manufacturers of products other than pacemakers have. In general, such design changes are implemented so that one single design can be shipped to all sales destinations.

Historically, European medical device regulation has been handled individually by each nation, and device regulation did not cover all devices. The European Union's (EU) new unified regulatory scheme is not yet entirely in place. When that system becomes fully effective, all electrical products will be subject to EMC requirements addressing both emissions and immunity. Medical devices in particular will be governed by their own dedicated set of regulations.

For devices currently subject to significant regulation, compliance with local EMC standards is often a requirement for product approval and major changes to comply with the new standards will in most cases not be necessary. However, a result of increased European interest in EMC has been some limitation in the export of some older equipment designs. At the end of 1996, when compliance with the EMC Directive becomes mandatory, some of these older designs with long-term, proven safety records will be withdrawn from the market. It is often impossible to upgrade such older designs, and when it is possible, it is generally too expensive to be practical.

Question 2. If the CTIA- and HIMA-sponsored project at the University of Oklahoma results in new EMC standards for future medical devices, how will HIMA member companies address the safety and efficacy concerns of products currently in the consumer marketplace? For example, if a pacemaker will require a change in shielding design, what steps will be taken for those individuals currently using implanted pacemakers?

Answer 2. HIMA is committed to working with CTIA and the facilities at the University of Oklahoma toward improving the EMI resistance of future medical devices. The intent of this work is not to produce standards, rather it is to develop information and understanding regarding the interactions between wireless communications devices (cellular phones) and medical devices. Any standards that may then be developed using that would apply only to new devices. Standards are intended for application to new devices. They are generally not applied retroactively, and frequently cannot be so applied.

If serious concerns regarding the safety and effectiveness of devices are uncovered, some design changes will be necessary. However, design enhancements are difficult and sometimes impossible to implement. Consequently, they will be used only when patient/user risk is very high. Most commonly these issues will be addressed through labeling and education to increase user awareness.

Information to date indicates that the risk to pacemaker patients is limited, both in scope and severity. We believe that providing information to pacing physicians and patients on the potential interaction between pacemakers and cellular phones, along with simple steps that can be taken to eliminate the interaction, are sufficient. The pacemaker industry is currently developing labeling information that can be provided with the pacemaker.

We also believe that the cellular phone industry shares this educational responsibility and should develop similar information to distribute with new cellular phones. We believe that the actions already undertaken by the pacemaker industry will provide a model for similar educational activities related to other medical devices.

Question 3. Please list the medical device companies which have been contacted by the Food and Drug Administration (FDA) about possible electromagnetic interference problems. For example, FDA officials cite their work with various wheelchair and apnea monitor manufacturers on developing new immunity design standards.

Answer 3. The FDA contacts many device companies regarding a broad spectrum of issues about which it has safety or other concerns. HIMA is not as a rule informed by the Agency of such contacts. Similarly, our member companies only contact us when they desire us to take an action regarding the FDA concerns. Thus, we cannot list specific manufacturers with whom the FDA has discussed electromagnetic interference (EMI) issues.

Some of the incidents that have been publicized were reported to the Agency by the affected companies under the FDA's Medical Device Reporting (MDR) regulation, which requires companies to report serious incidents that might have been caused by a medical device. The companies report to the Agency those incidents that they believe satisfy the MDR criteria that have been reported to them by device users or other sources.

EMI-related reports account for a very small fraction of the total reports sent to the Agency annually. In almost all cases, the EMI involvement was an initial conclusion drawn by the party that provided the information to the manufacturer.

Exclusive of the MDR system, the industry and the FDA have maintained an ongoing dialog that has encompassed many device types and has been conducted in a variety of fora.

As noted in the question, both powered wheelchairs and apnea monitors have been discussed by the FDA and the industry. The discussion on wheelchairs resulted in a letter to manufacturers recommending certain EMI-related labelling, while the apnea monitor discussions have focussed on the draft mandatory performance standard on which the FDA has been working for several years.

The FDA has also drafted reviewer's guidance for anesthesia and respiratory devices. Among other things, the guidance addresses EMI issues. The industry and the Agency have had several rounds of comments and discussions on this document.

Finally, it is important to note that both the FDA and the industry participate through organizations like the Association for the Advancement of Medical Instrumentation (AAMI), the American National Standards Institute (ANSI), and the international Electrotechnical Commission (IEC) on many voluntary standards efforts related to EMI. Similarly, both FDA and industry representatives participated in the recent EMI conferences in Ottawa and Dallas. All of these activities provide many opportunities for informal industry-Agency interaction regarding EMI.

Question 4. Mr. Stanley of the FCC testified that he believes that FDA should take the lead federal role on EMI-related matters. Would you agree?

Answer 4. We believe that the answer to this question depends heavily on the aspect of the EMI-related phenomenon that is being addressed. In general, if there are aspects of the issue that require regulatory action regarding medical devices, we would expect that FDA would have principal authority. Similarly, we would generally expect FCC to have principal authority in actions that require regulatory action regarding the wireless communications industry. The FCC is certainly the federal government's primary seat of expertise in electromagnetic communications matters, while the primary seat of expertise on medical devices resides in the FDA.

When we address interference between medical devices and wireless communications, we are addressing what most people would consider to be two vital and often complementary services. Neither can be sacrificed totally for the benefit of the other, particularly in light of the synergistic potential for the combination of these services.

HIMA believes that the best final outcome will be developed through cooperation between the agencies. Minimizing interference will be accomplished by the application of appropriate, cost-effective immunity measures to medical devices and the imposition of appropriate, cost-effective limitations on wireless communications services. The specifics of these solutions should be developed through an effort shared among both concerned industries and both concerned regulatory bodies.

Question 5. New standards for electromagnetic interference (EMI) have been established for GSM-standard digital cellular telephones operating in the European community markets. Does the HIMA have a position, either formal or informal, on these new European standards?

Answer 5. As a general rule, HIMA promotes the use of international standards developed by the major international standards organizations, ISO, IEC, and ITU. Unfortunately, HIMA does not have definitive knowledge of the EMI standards that govern cellular telephones of any kind in the EU, although to the best of our current understanding the standard for GSM phones is not yet final. It is our understanding that the EU so far as is possible applies international standards developed by IEC, CISPR, and the ITU, the international standards organizations addressing telecommunications.

Furthermore, all devices sold in the EU will have to comply with the EMC Directive, which specifies compliance with a number of CISPR standards addressing both immunity and emissions. For products like medical devices covered by a Directive governing a specific product area, the EMC requirements of the Directive governing the product will supersede those of the EMC Directive.

Question 6. Describe the level and scope of FCC staff communications and cooperation with the medical device manufacturing industry on EMI-related issues.

Answer 6. The FCC regulates the emissions of both intentional and unintentional radiators. This regulation covers the frequencies of radiation, but the medical device industry does not routinely communicate with the FCC staff. During the past decade, however, medical devices received a general exemption from the emissions testing required by Part 15 of the FCC regulations, ultrasound equipment was similarly exempted from the requirements of Part 18, and more recently, the FCC exempted magnetic resonance imaging (MRI) equipment from Part 18.

Other than the detailed interactions that were involved in developing these exemptions, contact between the medical device industry and the FCC has been largely incidental. Such incidental activities have involved individual license applications for medical telemetry systems and industry responses to FCC rule making proposals with potential effects on the medical device industry. A good example of such a proceeding was the FCC Notice of Inquiry a couple of years ago considering the adoption of the CISPR B standard for emissions as a replacement for the current FCC Part 18 regulations on which HIMA submitted formal comments.

O 127/200

ISBN 0-16-054917-5

90000

9 780160 549175